

Abatement Plan for Addressing the Opioid Crisis in Lake County and Trumbull County

Expert Witness Report of G. Caleb Alexander, MD, MS

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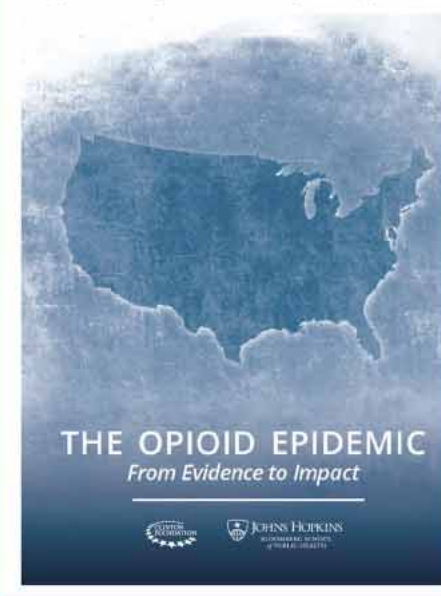
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I. BACKGROUND AND QUALIFICATIONS OF AUTHOR

1. My name is G. Caleb Alexander. I am a practicing general internist and Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health. I have been retained by Plaintiffs to provide my scientific expertise regarding the opioid epidemic, nationally and in the Ohio communities of Lake County and Trumbull County (the “*Communities*”). I have been asked to discuss ways to abate or reduce the harms caused by the opioid epidemic, which has devastated the Communities. I have also been asked to estimate the size of specific populations that may require abatement interventions within the Communities over a 15-year period, from 2021 to 2035, and to provide recommended cost estimates for certain abatement interventions (generally medical costs); the remaining costs are provided in the expert report of local economist Dr. Harvey Rosen. In his report, Dr. Rosen also calculates the total cost of my recommended abatement plan.
2. As a physician, I am responsible for the primary care of approximately 250 patients, most of whom live in and around Baltimore County. I have clinic one half-day per week and I am also responsible for patient care matters that arise at other times. The patients that I see range from young adults to nonagenarians (aged 90 – 99 years), and as a primary care physician I oversee their acute, preventive, and chronic needs, which include conditions such as asthma, diabetes, hypertension, osteoporosis, chronic pain, anxiety, and depression. While I do not specialize in the care of patients with opioid use disorder (OUD),^a I have patients in my practice with OUD who I co-manage with addiction specialists, and I care for patients who have lost family members to fatal opioid overdoses.
3. In contrast to my work as a physician, as a pharmacoepidemiologist, I focus on “the study of the uses and effects of drugs in well-defined populations.”¹ Pharmacoepidemiology is a bridge discipline that combines insights and tools from clinical medicine, pharmacology, and epidemiology to generate fundamental new knowledge regarding the utilization, safety, and effectiveness of prescription drugs. It also concerns itself with understanding the effects of pharmaceutical policy, such as regulatory or payment policies that influence prescription drug use. As a pharmacoepidemiologist, much of my work has focused on the nature, quality, and determinants of prescription drug utilization in the United States, although I have also conducted or participated in many investigations examining the safety of specific products. I have used many different data for this work, often data that has already been assembled for other purposes, such as administrative claims data from health plans or large national surveys.

^a Definitions of terms such as “opioid use disorder,” “addiction,” “non-medical opioid use,” and “misuse” are provided in the Expert Report of Dr. Anna Lembke.

Figure 1. Report on the Opioid Epidemic



4. During the past decade, I have devoted much of my professional time to addressing the opioid epidemic. I have served as one of three Co-Editors of monographs issued by the Johns Hopkins Bloomberg School of Public Health providing comprehensive, concrete, evidence-based solutions to the epidemic. These monographs were issued in October 2015 and October 2017 (**Figure 1**); the latter report is provided as **Appendix A**. I have also testified in front of the U.S. Senate and the U.S. House of Representatives; briefed groups such as the National Governors Association, the Food and Drug Administration, Congressional Black Caucus, Centers for Medicare and Medicaid Services, and the National Academy of Science, Engineering and Medicine; and participated in efforts to improve the safe use of prescription opioids within Johns Hopkins Medicine and other health systems. My work focused on the epidemic has been funded by the Department of Health and Human Services Assistant Secretary for Planning and Evaluation (DHHS/ASPE), the Centers for Disease Control and Prevention (CDC), the Robert Wood Johnson Foundation, and the National Institutes of Health (NIH).
5. I have published extensively about opioids, including analyses of prescription opioid use in the U.S.^{2,3} as well as evaluations of the structure and impact of regulatory^{4,5,6,7,8,9,10,11,12,13,14,15} and payment^{16,17,18,19,20} policies on opioid prescribing, dispensing, and utilization.²¹ I have also co-authored policy perspectives;^{22,23} a widely referenced public health review of the epidemic;²⁴ analyses of the potential impact of the coronavirus pandemic on the care of individuals with OUD;^{25,26} and an evaluation of the public health impact of select abatement remedies in the U.S.²⁷
6. In addition to these studies, I have also led or participated in teams examining many other facets of the crisis, including: availability of naloxone in retail pharmacies;²⁸ opioid initiation among members of households with a prescription opioid user;²⁹ the effect of reformulated Oxycontin on opioid utilization;³⁰ physicians' knowledge and attitudes regarding non-medical opioid use;³¹ use and impact of medications for addiction treatment (MAT);^{32,33,34,35} the costs and healthcare utilization associated with high-risk opioid use;³⁶ use of automated algorithms to identify non-medical opioid use;³⁷ the relationship between high-risk patients receiving prescription opioids and high-volume prescribers;³⁸ opioid use and safety among individuals with HIV,^{39,40,41} chronic kidney disease,^{42,43,44,45} or recent surgery;^{46,47,48,49,50} increasing prevalence of synthetic opioids in the illicit drug supply;^{51,52} and potential financial conflicts of interest among organizations opposed to the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain.^{53,54}
7. The studies I have performed examining the opioid epidemic have used a variety of epidemiologic methods, including: descriptive analyses based on cross-sectional, serial cross-sectional, and period prevalence designs; retrospective cohort studies using difference-in-difference, interrupted time-series, comparative interrupted time-series, and time-to-event designs; prospective cohort studies; qualitative assessments using grounded theory; and narrative and systematic reviews. A complete list of my publications is contained in my curriculum vitae (**Appendix B**).
8. In the first bellwether trial case in *In re: National Prescription Opiate Litigation* before Judge Dan Polster in the Northern District of Ohio, I served as an expert witness regarding how to best abate the opioid epidemic in Cuyahoga and Summit Counties. Since then, I have served as an expert witness in other

opioids-related litigation and, in some cases, provided deposition testimony, in both state and federal courts as outlined in **Appendix C**.

9. I received a B.A. cum laude from the University of Pennsylvania (Philosophy) in 1993, an M.D. from Case Western Reserve University in 1998, and an M.S. from the University of Chicago in 2003. A more complete description of my qualifications is found in my curriculum vitae. I performed this work through Monument Analytics, a health care consultancy that I cofounded that is separate and distinct from Johns Hopkins, and I was assisted during this process by Monument Analytics' employees and consultants. My rate of compensation for this matter is \$900 per hour. I am also reimbursed for my out-of-pocket expenses. I am not compensated based on the outcome of this matter nor the substance of my report.
10. The opinions and conclusions in this report are based on the information and documentation that was available to me at this time, and they are my own, rather than those of Johns Hopkins University. I reserve the right to supplement and revise these perspectives based on additional evidence or information that is made available to me after the date of this report.

II. DATA SOURCES, METHODOLOGY AND OPINIONS

11. In preparing this report, I reviewed materials from a number of sources, including: Bates-stamped documents and deposition testimony in this case provided to me by counsel; published reports regarding the epidemic; information derived from other local and national sources; and peer-reviewed literature, whitepapers, reports from public health authorities, non-profit organizations, and other publicly available sources. I, along with some of my team members, have also spoken with local stakeholders including:

- Lauren Thorp, MS, Director of Recovery & Youth Programs at Trumbull County Mental Health & Recovery Board
- April Caraway, Executive Director at Trumbull County Mental Health & Recovery Board
- Kim Fraser, MS, Executive Director at Lake County Board of Alcohol, Drug Addiction and Mental Health Services

Many of my findings are based on prior investigations that my team and I have either performed or synthesized, such as knowledge contained in **Appendix A** and in citations such as references #1-#54. A complete list of the documents I consulted in preparing this report is provided as **Appendix D**.

12. Several prior reports, such as the Community Health Improvement Plans for Lake⁵⁵ and Trumbull⁵⁶ Counties, Trumbull County Community Health Assessments,^{57,58} Ohio Substance Abuse Monitoring (OSAM) Network reports,⁵⁹ and the Recovery Ohio Advisory Council Initial Report⁶⁰ are relevant to my report given their authorship and focus. The population estimates presented in my Redress Models, enclosed as **Appendix E**, are derived from data from local government entities (e.g., Ohio Department of Mental Health and Addiction Services [OhioMHAS]), federal agencies (e.g., Centers for Disease Control and Prevention [CDC], Substance Abuse and Mental Health Services Administration [SAMHSA], Department of Justice), community-based organizations, peer-reviewed publications, and both my and others' expert opinion. The selection of each estimate was driven by the strength of evidence and appropriateness of the data for the specific context at hand. I discuss my approach to evaluating evidence further in Paragraphs #15 and #16. Overall, I took a conservative approach to derive the population estimates included in my Redress Models.
13. The layout of my Redress Models mirrors the layout of this report. For each abatement intervention, I list the estimated size of the target population, how it was derived and the sources that I used. For example, I used data from the United States Fire Administration and Ohio Department of Public Safety to estimate the number of first responders (firefighters, emergency medical technicians [EMTs] and paramedics, and police officers) in the Communities that should be provided with naloxone and trained regarding its use. For each abatement category, I first estimate the size of each relevant population for 2021 and then I project how these populations are likely to change over a fifteen-year period from 2021 through 2035. For example, I project changes in the number of first responders using annual employment growth rates based on data from the Ohio Department of Job and Family Services. More information regarding the sizes of different populations, as well as the methods that I used to project them over time, is provided within the Redress Models.
14. In addition to the Redress Models, I was asked to review the literature on certain potential indicators of high risk opioid distribution and describe their evidence base. See **Appendix F**.
15. In all cases, my review of the scientific evidence base was based on a stepwise process building on the foundation of literature regarding the opioid epidemic that I was already aware of. To supplement this, I reviewed the content of additional academic and governmental studies, including both their reference lists as well as subsequent reports that have cited them. I also reviewed reports such as those discussed in Paragraph #11 for additional sources of scientific information. Finally, in some instances, additional

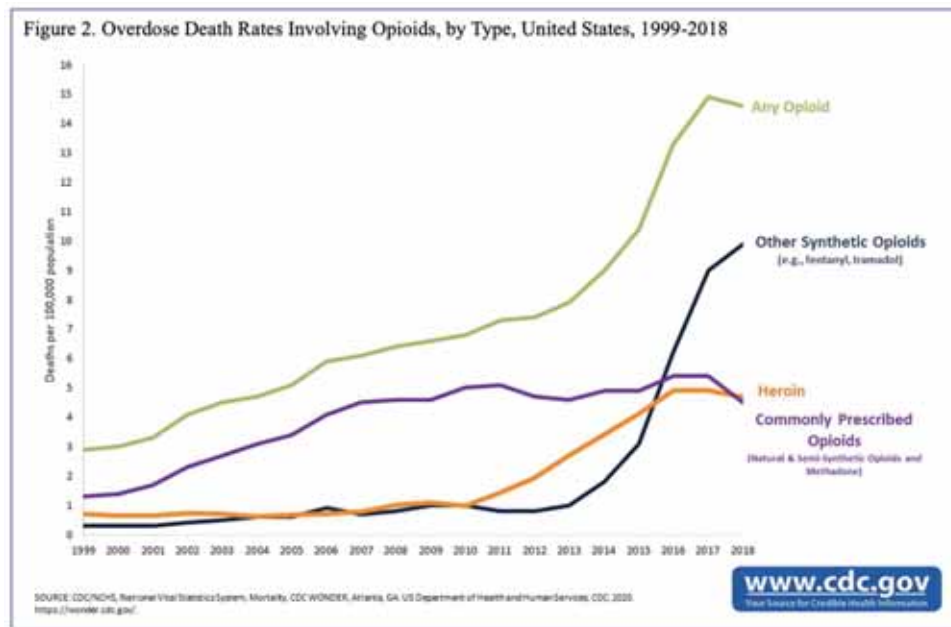
candidate articles were identified based on keyword searches of major bibliographic databases such as PubMed. In evaluating studies, I used a number of qualitative criteria that are often useful in evaluating the strength of scientific evidence supporting a given scientific finding or claim. These include factors such as the publishing journal, authorship team, affiliated institutions, funding source(s), data source(s), methodologic approach, and interpretation.^b The “Hill Criteria” (strength of association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy) are also an important means of evaluating the strength of causal inference possible from a given scientific study, and I have applied these criteria as well.⁶¹

16. For some remedies to abate the opioid epidemic in the Communities, such as OUD treatment or naloxone distribution and training, the evidence base is vast, with thousands of peer-reviewed manuscripts examining this matter. In these settings, formal evidence syntheses were often available, typically systematic reviews that represent a pre-specified, transparent, reproducible, highly structured approach to curating and critically appraising the totality of information required to address a carefully specified question. Because of their comprehensiveness and rigor, such evidence syntheses are often regarded as at the top of the “evidence pyramid.”⁶² For some abatement interventions, I also used information available from authoritative sources such as the CDC, National Institute on Drug Abuse (NIDA), or SAMHSA.
17. There is widespread consensus in both clinical and public health communities that the abatement measures identified in this report are effective in reversing opioid-related morbidity and mortality. The measures discussed herein are consistent with Governor DeWine’s RecoveryOhio Advisory Council,⁶³ and have been put forth by numerous consensus panels, task forces, professional society organizations and others. Disagreement about these solutions, when present, has tended to focus more on the priority of the interventions given limited funding (e.g., how much should be spent on law enforcement vs. medications for addiction treatment [MAT]),⁶⁴ as well as in some cases, the potential unintended effects of some interventions. Fortunately, there is a large evidence base to guide the selection of interventions that should be undertaken in the Communities, and also a recognition of the critical point, as expressed by former Congressman John Delaney, “that the cost of doing nothing is not nothing.”⁶⁵
18. I conclude that an opioid epidemic currently exists within Lake County and Trumbull County. This epidemic continues to result in high levels of opioid-related morbidity and mortality as described in this report and in materials that I have reviewed to prepare it. I further conclude, based on my experience in epidemiology, clinical medicine, and public health, my extensive application of these fields to the opioid epidemic and my analysis in this case, including review of the local Communities’ materials, that I am able to determine what additional evidence-based and evidence-informed measures and approaches should be used to reduce opioid-related harms. These measures and approaches are described below. The specific utilization and combination of measures should be subject to the opinions of stakeholders, policy-makers, and subject matter experts in the Communities.
19. The next sections of my report discuss indicia of the opioid epidemic in the United States as well as the Communities. After that, I discuss principles that should govern an effective response, misconceptions that must be addressed, and the importance of customizing abatement efforts to the needs of the Communities’ unique culture and heritage.

^b Neither these criteria nor the Hill Criteria are absolute. Rather, they serve as contextual factors that provide qualitative information that can be useful in examining the credibility of scientific claims.

III. INDICIA OF OPIOID CRISIS AND ABATEMENT EFFORTS IN LAKE COUNTY AND TRUMBULL COUNTY

20. Between 1992 and 2010, the volume of opioids prescribed in the U.S. increased by approximately 400 percent.⁶⁶ Rates of addiction, overdose deaths, and many other opioid-related harms increased in parallel.⁶⁷ Between 1999 and 2019, nearly 500,000 individuals in the U.S. died from an opioid overdose.⁶⁸ In 2017 alone, an estimated 47,600 people died in the U.S. from opioids, more than from motor vehicle accidents, suicide, gun violence, or deaths at the peak of the AIDS epidemic.⁶⁹ For each year between 2015 and 2017, life expectancy in the U.S. declined, fueled in part by the epidemic.⁷⁰ The origins of the present-day national opioid epidemic are described further in the Expert Report of David Herzberg.



21. As observed nationally and within Ohio, there was first a rise in prescription opioid-related deaths in the early 2000s, followed by a rapid increase in heroin overdose deaths beginning in 2010, and a sharp increase in fentanyl overdose deaths in 2016 (**Figure 2**).^{71,72} The impact of illicit fentanyl has been especially severe in the Communities, relative to other areas in the U.S.^{73,74} There is a clear link between non-medical use of prescription opioids and subsequent heroin or illicit fentanyl use, as heroin and fentanyl are close chemical analogues to prescription opioids.⁷⁵ Several studies estimate that 70-80% of current heroin users report non-medical prescription opioid use prior to initiating heroin.^{76,77} However, a recent study of individuals with OUD in Ohio found that nearly 90% of participants used prescription opioids prior to initiating heroin.⁷⁸ In 2019, over four in five (83.7%) overdose deaths in Ohio involved an opioid and over three in five (76.2%) overdose deaths involved fentanyl.⁷⁹ Though the number of overdoses decreased slightly during 2018 and 2019 from the all-time high in 2017, Ohio has experienced a sharp surge in opioid overdose deaths between March and June 2020.⁸⁰ Within three months, the opioid overdose death rate increased to 11 per 100,000 Ohioans, more than the previous 10-year high of 10.87 per 100,000 in 2017.
22. Fortunately, according to data from the Ohio Automated Rx Reporting System (OARRS), the Communities have experienced a decrease in the average number of opioid pills per resident. For example, in Lake County, the average number of opioid pills exceeded 60 per resident each year between 2010 and 2014; followed by a decrease to an average of 30.7 pills per resident in 2019.⁸¹ Similarly, between 2010 and 2014, the average number of opioid pills exceeded 88 per resident per year in Trumbull County; followed by a decrease to an annual average of 71.9 pills per resident in 2017 and 52.5 in 2019. However,

the magnitude of decrease in opioid doses per patient, rather than per capita, has been smaller. For example, between 2010 and 2019, the number of opioid pills per patient in Lake County decreased from 271.8 to 218.2. The number of opioid pills per patient have remained around 30% higher in Trumbull County than Ohio overall, with 346.6 pills per patient in 2010 and 322.8 pills per patient in 2019. From 2014 to 2019, the age adjusted drug overdose death rate was 1.6 times higher in Trumbull County than Ohio overall (53.3 vs 33.6 per 100,000, respectively).^{82,83}

23. Like many Ohio communities, Lake and Trumbull Counties have experienced a devastating loss of life due to opioid overdoses. For example, from 2014 to 2019, the age adjusted drug overdose death rate was slightly higher in Lake County than Ohio overall (34.7 vs 33.6 per 100,000, respectively).⁸⁴ Between 2015 and 2016, the number of individuals that died from heroin and fentanyl overdoses in Lake County doubled from 38 to 81.⁸⁵ The number of individuals who died from heroin and fentanyl overdose remained high in 2017 (80 deaths) followed by a decrease in 2018 (61 deaths). However, between February and June 2020, the Lake County General Health District reports that the number of drug overdoses has increased by 77% from 31 to 55.⁸⁶
24. Trumbull County has also been hard hit. Between 2014 and 2016, the number of individuals that died from heroin and fentanyl overdoses in Trumbull County tripled from 32 to 94.⁸⁷ The number of individuals who died from heroin and fentanyl overdose remained high in 2017 (107 deaths) followed by a decrease in 2018 (65 deaths). According to the Trumbull County Coroner's Office, fentanyl was involved in 91% of the drug overdose deaths in 2019.⁸⁸ ED visits for suspected drug overdose peaked in 2017 at 1,272 visits (or a rate of 139.3 per 10,000 ED visits), followed by a decrease in 2018 and 2019 to 645 and 952 visits (or a rate of 82.8 and 98.1 per 10,000 ED visits, respectively).⁸⁹ In 2018-2019, four to five percent of the adult population in Trumbull County, reported that they misused prescription opioids within the previous six months.⁹⁰
25. Families and children within the Communities have also been impacted by the opioid epidemic. Between 2016 and 2018, the number of neonatal abstinence syndrome (NAS) increased from 24 to 28 in Lake County and from 46 to 55 in Trumbull County.^{91,92} Though much is still unknown regarding the long-term trajectories of children with NAS, young children born with NAS have increased risk of socio-behavioral abnormalities⁹³ and poorer school performance⁹⁴ indicating that neurocognitive and physical effects may persist through adolescence and require expanded services into adulthood.⁹⁵ There has also been an increase in the number of children being placed in foster care or kinship care, such as being raised by grandparents. In a briefing of the opioid epidemic's impact on children services in Ohio, the Public Children Services Association of Ohio reported a 62% increase in the number of children in Ohio placed in custody with a relative between 2010 and 2016.⁹⁶
26. Harms from the opioid crisis have not gone unchecked, and despite a severe lack of resources, the Communities have nevertheless mobilized in many ways to address these challenges, including through prevention efforts such as take-back programs; naloxone distribution and training through Project DAWN; and treatment such as through the provision of medications for addiction treatment (MAT). Similarly, concerns regarding the effect of OUD on pregnant women, new mothers and infants have led to efforts in the Communities' systems of care to manage OUD among expectant mothers and their offspring. In addition to universal screening of pregnant women, MAT is available to women through the Maternal Opioid Medical Support (MOMS). Within Trumbull County, the Alliance for Substance Abuse Prevention (ASAP) Coalition, a project of the Trumbull County Mental Health and Recovery Board that was founded approximately 15 years ago, works as a bridge between substance abuse support services, treatment providers, and other members of the community to try to prevent and address substance use.⁹⁷ Their goals are to reduce substance use in the community, decrease overdose, and increase treatment referrals.⁹⁸

27. Despite these gains, many barriers persist, many programs and initiatives are vastly under-resourced, and there are other signs that the epidemic is as active as ever.⁹⁹ As described in a June 2019-January 2020 surveillance report from the Ohio Substance Abuse Monitoring (OSAM) Network, individuals that misuse opioids reported a decrease in the supply of unadulterated heroin and an increase in fentanyl and fentanyl mixing with other drugs.¹⁰⁰ These findings may reflect the changing preferences of people who use drugs and growing tolerance to opiates.¹⁰¹ According to the OSAM Networks report, treatment providers in the region have observed that patients will use “heroin” and “fentanyl” interchangeably as well as an increase in young users of heroin in the Cleveland region following the introduction of fentanyl. Additionally, people with OUD in Ohio report using methamphetamine and other substances to alleviate their opiate withdrawal symptoms,¹⁰² which in turn, increases the prevalence of polysubstance use. This is further reflected in a study of individuals with OUD in Ohio, which found that nearly nine in ten reported using illicit opioids prior to initiating methamphetamine use,¹⁰³ highlighting the need to provide comprehensive and adaptable treatment services for individuals in the Communities.^{c,104}
28. As we¹⁰⁵ and others^{106,107,108} have argued, the novel SARS-CoV-2 coronavirus (COVID-19) pandemic injects new urgency into efforts to address the opioid epidemic, given that it comes at a time when our country’s response to the opioid epidemic was just starting to coalesce. One major concern is that the pandemic has disrupted care, including access to medications for addiction treatment, for many with opioid use disorder. Fortunately, SAMHSA,¹⁰⁹ the Drug Enforcement Administration,¹¹⁰ and the Center for Medicare and Medicaid Services have responded by relaxing or clarifying rules and regulations so as to allow for greater provision of take-home methadone, remote prescription of controlled substances and reimbursement for telehealth services. Another concern is that many individuals with OUD have chronic comorbid conditions, as well as tobacco use, which place them at higher risk from critical illness or death should they become infected with COVID-19.¹¹¹ Yet a third major concern arises from the fact that addiction is “a disease of isolation.” For an already marginalized group, social distancing and other measures instituted in response to the global pandemic pose particularly profound risks. As we argue in our recent analysis, referring to response efforts underway to meet the needs of those impacted by the opioid epidemic, “These efforts will require new partnerships, unprecedented use of technology, and the dismantling of antiquated regulations. The greatest strength of the treatment system has always been compassion and care for the most vulnerable—qualities needed now more than ever.”¹¹²

^c Thus, the increasing presence of synthetic opioids in illicit drugs such as cocaine and methamphetamine, as well as rising stimulant-related deaths, has raised new concerns. As discussed elsewhere (e.g., Part VI), polysubstance use is common among individuals with OUD. While a comprehensive review of other use disorders (e.g., tobacco, alcohol, stimulants) is beyond the scope of this report, abatement approaches to reduce opioid-related harms must be informed by the presence of other use disorders among many with OUD.

IV. PRINCIPLES GOVERNING EFFECTIVE RESPONSE

29. Despite the unprecedented injuries and deaths from the opioid epidemic, there is virtual consensus in the clinical, public health, and health policy communities that the epidemic can be abated. This consensus is reflected in the high concordance between a November 2017 report from the last Administration regarding the opioid epidemic,¹¹³ a report that I Co-Edited and was released by the Johns Hopkins Bloomberg School of Public Health,¹¹⁴ and other groups' recommendations to prevent further harms.^{115,116,117} The Johns Hopkins report, enclosed as **Appendix A**, stemmed from three principles (**Figure 3**) that provide a valuable basis for current efforts.

Figure 3. Principles Governing Johns Hopkins Report: "The Opioid Epidemic: From Evidence to Impact".

- Informing Action with Evidence
 - Scaling up evidence-based interventions; rapidly implementing and evaluating promising policies and programs
- Intervening Comprehensively
 - All along supply chain; clinic, community and addiction treatment settings; primary, secondary and tertiary prevention; creating synergies across different interventions
- Promoting appropriate & safe opioid use
 - Reducing overuse; focus on safe use, storage and disposal; optimizing use in accordance with best practices

30. In order to abate the epidemic, it is also important to eliminate common misconceptions about opioids and the ensuing epidemic, since inaccurate, misleading or false statements about the epidemic have allowed it to flourish. Examples of such misconceptions include:

Misconception #1: If a patient has "organic" pain, one need not worry about the addictive potential of opioids.

Reality: There is no evidence that organic pain prevents opioid addiction, and the notion that opioids are typically safe for chronic, non-cancer pain has contributed to their vast overuse.

Misconception #2: The primary driver of the epidemic is one of abuse, rather than addiction.

Reality: Abuse is a behavior and addiction is a disease; there are many lines of evidence demonstrating that addiction, rather than abuse, is the primary cause of opioid-related morbidity and mortality.

Misconception #3: The epidemic is largely driven by devious individuals such as rogue physicians and patients who are "doctor-shoppers."

Reality: Rogue physicians and "doctor-shoppers," while very important to identify and manage, account for a small proportion of opioid-related harms.

Misconception #4: If we constrain access to prescription opioids, it will just push people to heroin.

Reality: There are many factors that contribute to heroin use, and the potential for opioid policies "pushing" people to heroin underscores the need for significant treatment expansion in the United States.

V. ABATEMENT FRAMEWORK

31. There are three major categories of remedies that must be undertaken to address the opioid epidemic in the Communities.^{d,e} First, we must improve the opioid prescription practices and the treatment of pain, since opioid oversupply has been a key driver of the epidemic.^{118,119} Second, we must identify and treat individuals with OUD. This is important because even if prescription opioids were to be responsibly marketed, promoted, and used beginning tomorrow, there are still thousands of individuals with OUD in the Communities, many of whom require active treatment and all of whom deserve access to care if and when treatment or recovery services are sought. Third, we must customize abatement remedies for specific subpopulations of the Communities, including: pregnant women, new mothers, and infants; adolescents and young adults; families and children; the homeless and those with housing insecurity. We must also address the large number of individuals who may misuse opioids but who do not yet fulfil formal criteria for OUD.
32. No *single* abatement remedy that is proposed can fully address the oversupply of opioids and associated morbidity and mortality in the Communities; there are no magic bullets, and this underscores the importance of intervening comprehensively as noted in the Community Health Improvement Plans for Lake¹²⁰ and Trumbull¹²¹ Counties. Also, some of the abatement remedies discussed may interact with one another in synergistic fashion, and successful implementation of some strategies may be dependent upon the simultaneous intervention of other strategies. For example, initiatives to decrease stigma and educate law enforcement and other community members about addiction may increase the demand for treatment, while expansions in treatment capacity to meet such demand may decrease rates of active OUD, which in turn may decrease overdose deaths and the need for naloxone. The dynamic nature of the epidemic, as well as the potential for these sorts of interactions, speaks to the vital need for surveillance and leadership as outlined in Section 1F. This will maximize the ability of communities to respond effectively to near real-time intelligence regarding key parameters of the epidemic and thus to use, and redirect, resources to maximize their public health value.
33. Some abatement approaches may be framed in the context of looking forward ten or fifteen years.^f However, the legacy of the opioid epidemic will endure in the Communities far beyond that. This is because while OUD can be treated and may remit, it is not curable, and some individuals with OUD will require treatment indefinitely.^{122,123,124} Others have acquired HIV and/or hepatitis C as a result of an addiction that began with prescription opioids,^{125,126} and they may require indefinite care for these comorbid conditions. Foster care for those orphaned by the epidemic, child protective services, and services for children impacted by opioid use in utero must be resourced to address the needs of children and young adults as they grow and develop. Opioid use and its sequela also contribute to intergenerational trauma that propagates throughout time. For many, living healthy, productive lives in recovery is an active process, and thus to be successful, individuals must be supported with long-term resources to maximize their opportunities for success.

^d Other interventions are important in addressing the epidemic yet beyond the scope of this report, such as changes to coverage and reimbursement policies so as to improve options for pain treatment and reduce financial barriers to OUD treatment.

^e While there are other ways to classify potential remedies, the elements within these remedies are remarkably consistent across different abatement proposals put forth locally and nationally, reflecting the widespread consensus about what needs to be done.

^f This medium-term view strikes a balance – it is long enough to support infrastructure development and several cycles of planning and evaluation while avoiding some of the uncertainty entailed in trying to anticipate the magnitude of sequelae from the epidemic that may last decades or even generations.

34. Here and throughout, while I suggest remedies that should be included as part of a comprehensive abatement plan, and while I consider programs that are already underway, I leave it to the Communities^g to determine the degree to which further investment should be undertaken.

For each of the categories below, in the following sections of my report, I provide background and scientific context, components of the proposed abatement interventions corresponding to each category, and concluding thoughts. Population estimates for each category are provided in the Redress Models (Appendix E).

- Category 1: Prevention – Reducing Opioid Oversupply and Improving Safe Opioid Use
 - 1A. Health Professional Education
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 - 3A. Public Safety
 - 3B. Criminal Justice System
 - 3C. Vocational Training, Education, and Job Placement
 - 3D. Mental Health Counseling and Grief Support
- Category 4: Addressing Needs of Special Populations
 - 4A. Pregnant Women, New Mothers, and Infants
 - 4B. Adolescents and Young Adults
 - 4C. Families and Children
 - 4D. Homeless and Housing Insecure Individuals
 - 4E. Individuals with Opioid Misuse

^g Stakeholders include, but are not limited to, public health and law enforcement; treatment providers and systems; behavioral health providers and systems; educators; community advocates; employers; payers; and the courts.

CATEGORY 1: PREVENTION – REDUCING OPIOID OVERSUPPLY AND IMPROVING SAFE OPIOID USE

The goal of this category is to reduce the widespread oversupply of prescription opioids in the Communities so as to decrease injuries and deaths from these products.^h This is important because the oversupply of prescription opioids during the past two decades has been an important driver of the opioid epidemic, both locally and nationally.ⁱ Harm from this oversupply arises from many points in the continuum of care, ranging from how clinicians treat pain to the diversion of opioids throughout the supply chain.

A. Health Professional Education

The goal of this remedy is to train health care providers, including prescribers and other health care personnel – including those employed by the Lake and Trumbull Counties – such as dispensers (pharmacists) and emergency medical technicians (EMTs), regarding the appropriate use of opioids in clinical practice, as well as how to identify and appropriately respond to patients who may have OUD. This is important because historically, many providers have overestimated the effectiveness of opioids and/or underestimated their risks. This has contributed to the oversupply of opioids, not only with respect to whether they are used at all, but also with respect to the dose and duration of use. In addition, OUD is often not recognized in clinical practice, and even when recognized, the delivery of treatment and recovery services often falls short.

35. One of the most systematic and well-studied approaches to direct training of prescribers, sometimes referred to as “academic detailing,” should also be employed. Academic detailing is a method of evidence-based, interactive outreach to prescribers that uses trained personnel to make face-to-face visits with clinicians to promote optimal prescribing and improve the quality of patient care. Established in the 1980’s, there are dozens of studies that provide evidence of its value,^{127,128,129,130} including a recent investigation indicating large decreases in opioid prescribing following a multi-level intervention that included academic detailing.¹³¹ A systematic review of the impact of provider education, the most comprehensive assessment of its kind, concluded that this strategy results in significant improvements in prescribing quality,¹³² and this narrative is consistent with a large literature overview examining the effectiveness of interventions to shape prescriber behavior.¹³³
36. In addition to the numerous studies summarizing the evidence base for academic detailing outlined above, some studies have also examined the potential impact of such education on opioid-related measures. For example, a quality improvement study comparing a six-month pre-intervention baseline with a 16-month post-intervention period ending in April 2018 at a regional health system in Maryland documented a nearly 40% decrease in the overall opioid prescription rate, a 60% decrease in the quantity of opioids prescribed per visit, and a reduction in the strength of opioids prescribed following a public and provider education campaign.¹³⁴ Patient satisfaction surrounding pain management in the emergency department also improved. Similarly, a multi-modal intervention between 2010 and 2015 using surveillance, academic detailing, and clinical decision support tools within Kaiser Permanente Southern California was associated with a 30% reduction of high-dose opioids, 98% reduction in large quantity (i.e., over 200 pills) opioid dispensing, and a 72% reduction of long-acting and extended-release opioids among 3.2 million adults in the Kaiser Permanente Southern California system.¹³⁵
37. Academic detailing has also been used to increase naloxone use.^{136,137} For example, an analysis of Veterans Affairs (VA) facilities between 2014 and 2017 found that facilities that received academic detailing had a rate of naloxone prescribing that was five times higher than their counterparts.¹³⁸ Of the

^h This category excludes consideration of Drug Enforcement Agency (DEA) quotas, controlled substance scheduling and other mechanisms the federal government may use to reduce supply of opioids or precursors in the marketplace.

ⁱ Reductions in opioid oversupply will also decrease opioid demand, since opioids are highly habit forming, tolerance quickly develops and a substantial minority of individuals receiving chronic opioids develop OUD.

estimated increase of 15,000 naloxone prescriptions among facilities receiving academic detailing, two-thirds went to patients at a high risk of overdose due to the quantity or type of opioids prescribed. Another study, of 40 primary care providers in San Francisco, found that those receiving detailing had a ten-fold higher rate of prescribing naloxone than their counterparts;¹³⁹ physician participants reported that as a result of the educational outreach, they were able to open new conversations with patients to promote safer and more compassionate care.

38. Efforts to reduce the oversupply of opioids should be coupled with information regarding the principles of sound pain management, including through a focus on comprehensive assessments, multidisciplinary management, and functioning rather than pain levels per se. Opioids represent just one of a large number of pharmacologic and non-pharmacologic treatments that providers and patients may use for the treatment of pain. Alternative pharmacologic treatments include acetaminophen, non-steroidal anti-inflammatories (NSAIDs), antidepressants, anticonvulsants, and topical analgesics;¹⁴⁰ while non-pharmacologic treatments for pain include increasing physical activity or exercise, physical therapy, occupational therapy, chiropractic care, and psychological interventions.¹⁴¹ In addition, the care of pain among those already engaged in opioid misuse or with OUD requires additional skill and training given the need for clinical management of both.
39. Training on the management of patients who have been maintained on chronic opioids is also important, especially the subset of patients on high-dose opioids (e.g., greater than 90 morphine milligram equivalents per day). Since patients using opioids chronically are physically dependent on them,^j they must not have their opioids abruptly discontinued, nor should tapering be performed unilaterally. An increasing number of guidelines for tapering opioids among these individuals are available.^{142,143} These guidelines include information on when tapering should be considered among patients on long-term opioid treatment, which often occurs when adverse effects or the risk of adverse effects (e.g., sedation, drowsiness, constipation, nausea) outweigh potential benefits with respect to reductions in pain and improvements in physical, psychological and/or social functioning.¹⁴⁴ The guidelines also speak to the optimal management of individuals who, based on taper failure, may fulfil criteria for persistent opioid dependence and who may be best managed through long-term opioid treatment, such as buprenorphine or methadone.
40. While there are many criteria that could be used to select physicians who should receive academic detailing, a conservative approach would be to focus on approximately 10% of all active, ambulatory patient-care prescribers – those that account for the highest prescribed opioid volume.^k Because opioid prescribing is highly skewed, such a focus, properly designed, could reach prescribers accounting for the majority of opioids in the marketplace. For example, we previously found that fewer than 5% of prescribers in Florida accounted for approximately two-fifths of opioid prescriptions and two-thirds of opioid volume during a given calendar year.¹⁴⁵ Similarly, a study of workers compensation claims in California indicated that approximately 87% of opioid volume was accounted for by the top 10% of prescribers.¹⁴⁶
41. Since academic detailing should target high volume prescribers in the Communities, it must be based on information regarding specific individuals' prescribing behaviors. One source of such information would be Ohio's Prescription Drug Monitoring Program (PDMP), created by the Ohio Board of Pharmacy, the

^j Within a few weeks or less, all patients using opioids develop physical dependence, a predictable neurochemical change associated with sustained use. By contrast, addiction is far less predictable, represents compulsive use despite harm, and is often associated with impairment in social, psychological and/or physical functioning.

^k While this discussion focuses on ambulatory care, an increasing number of evidence-based guidelines are also available for the post-surgical setting, where opioids have also been heavily oversupplied; an academic detailing program should also be considered for these prescribers as well.

Ohio Automated Rx Reporting System (OARRS).¹⁴⁷ The OARRS is available to both prescribers and pharmacists, with information on controlled substances, gabapentin, life-threatening drug combinations (e.g., benzodiazepines and opioids), and identifies patients that use multiple doctors.¹⁴⁸ The OARRS contains county-level information and is integrated with electronic medical records and pharmacy dispensing systems. An alternative source of similar data would be from a market intelligence firm, such as Symphony Health or IQVIA. These companies license data regarding prescription drug prescribing to pharmaceutical companies and other clients, and may represent a source of more efficiently gathered, possibly better curated and more timely information regarding both physician and non-physician prescribers (e.g., advanced nurse practitioners, physicians' assistants).¹⁴⁹

42. The value of provider education lies in the quality of the information that is delivered. Thus, the information must be of the highest quality and from the most reputable sources. A natural foundation for this effort would be the 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, given the credibility of the CDC, the extraordinary rigor that was exercised in its development, as well as the widespread endorsement that it has received.^{150,1} This Guideline, which has been supplemented by more recent, CDC-funded systematic reviews,¹⁵¹ could be cross-referenced with other guidelines and sources used by established provider education programs already underway on opioids.¹⁵² Locally, the OhioMHAS provides Opioid Prescribing Guidelines, including information for health care providers on acute pain management, non-terminal chronic pain, and patient screening tools.¹⁵³ These guidelines are published by the Ohio Board of Pharmacy in partnership with healthcare and professional organizations from across Ohio.¹⁵⁴ In addition to delivering information about best practices, academic detailing should also include reports so that individual prescribers or dispensing pharmacists can review and critically evaluate their own prescribing or dispensing patterns relative to peers at local, regional, and national levels, as well as identify instances of prescribing or dispensing that may warrant closer and more critical evaluation.
43. Provider education has to deliver a limited number of focused messages or it will not be effective. The CDC Guideline for Prescribing Opioids for Chronic Pain includes twelve scientifically supported "clinical reminders" that can be used as a basis for provider education modules:
 - 1) Opioids are not first-line or routine therapy for chronic pain;
 - 2) Establish and measure goals for pain and function;
 - 3) Discuss benefits and risks, as well as the availability of non-opioid therapies with patients;
 - 4) Use immediate-release opioids when starting opioid therapy;
 - 5) Start with the lowest effective dosage and use caution when titrating the dose (avoid increasing dosages by ≥ 90 morphine milligram equivalents/day);
 - 6) When treating acute pain, prescribe quantities no greater than what is needed for the expected duration of pain that is severe enough to warrant opioids (often no more than 3 days);
 - 7) Follow-up and re-evaluate risks and benefits with patients as they continue opioid therapy, and should the harms of continued opioid therapy outweigh the benefits, taper to a lower dosage or taper and discontinue opioid therapy;
 - 8) Evaluate risk factors for opioid-related harms and incorporate risk mitigation strategies into treatment regimens;
 - 9) Utilize the OARRS data to determine whether a patient is receiving other therapies that put them at risk;
 - 10) Urine drug testing should be utilized to assess for the presence of other medications and illicit substances;

¹ While the 2016 CDC Guideline is one of the most comprehensive, authoritative and widely cited opioid guidelines, any academic detailing program as part of an abatement remedy should be based on an assessment of the most current and suitable sources of information for such a program. These guidelines will be updated by the CDC in 2021.

- 11) Avoid concurrent benzodiazepine and opioid treatment; and
- 12) Arrange treatment for patients with opioid use disorders.¹⁵⁵

44. The 2016 CDC Guideline improves upon clinical guidelines that emerged from the liberalization period in the 1990s in several important ways. For example, in 1997, the American Academy of Pain Medicine and the American Pain Society issued a consensus statement that endorsed the use of opioids to treat chronic, non-cancer pain, arguing that “studies indicate that the de novo development of addiction when opioids are used for the relief of pain is low.”¹⁵⁶ By contrast, the 2016 CDC Guideline underscores the risks of addiction and other adverse events related to prescription opioids, recommends lower dosages, focuses on improving safe use among all, rather than “high-risk,” patients, and provides more specific guidance regarding how to best monitor opioid use and establish thresholds for stopping them in the setting of unfavorable risks/benefit balance.¹⁵⁷
45. The National Resource Center for Academic Detailing (NaRCAD), a center aimed to support clinical outreach education programs, provides an extensive directory of established provider education programs, including a section for those dedicated to opioid safety.¹⁵⁸ For example, Alosa Health is a non-profit that has deep experience in this area conducting state- and nationwide campaigns.^{159,160} While pharmaceutical companies and pharmacy benefit managers (PBMs) both have extensive workforces available for direct prescriber outreach, neither would be credible in this setting given the conflicts of interest that would be posed. Instead, provider education programs typically recruit physicians, nurses, pharmacists or other individuals with a background in related health disciplines to conduct outreach.
46. Regardless of the detailer’s background, it is essential that educators have no potential commercial conflicts of interest, have a background in a health discipline such as medicine or pharmacy, and receive rigorous training on how to conduct this outreach. Lack of clinical knowledge may cripple the detailer’s credibility with the prescriber, making it difficult to establish a strong relationship that promotes rational prescribing. Furthermore, it is also important that the outreach is repeated over time, with follow-up visits to encourage positive changes and reinforce key messages.
47. In addition to academic detailing of prescribers, broader health professional education should also be considered for at least four types of health care providers in the Communities:
 - Licensed prescribers (beyond those selected for academic detailing based on high opioid prescribing), such as physicians, dentists, nurse practitioners, and physicians’ assistants, are important to target because they issue prescriptions for opioids and other analgesics.
 - Nurses, especially in settings such as Emergency Departments, urgent care, and other clinical areas where opioids are commonly used, should be targeted because they are in an influential position to shape the culture of pain management and to raise awareness about evidence-based methods to identify and treat pain and OUD.
 - Dispensers, or pharmacists, should be targeted because they dispense opioids and are increasingly responsible for implementing drug utilization management policies and practices designed by payers and PBMs.
 - Emergency medical technicians (EMTs) are important to reach because they are often the first point of contact with individuals who have overdosed, and thus in a key position to bridge a common treatment gap that contributes to low rates of evidence-based treatment for OUD, namely, individuals who are resuscitated but not connected with OUD treatment.
48. Resources permitting, education of other health care personnel, such as pharmacy technicians and physical therapists, should also be undertaken. Since opioid oversupply, as well as OUD, are both so common, these personnel also regularly engage with patients who have a high likelihood of being harmed by the

epidemic, and thus they too are in a position to support a required cultural shift in the paradigm of pain and OUD identification and management in the U.S.

49. In addition, while training and professional development of health care personnel such as doctors, nurses and EMTs is vital, additional educational capacity-building, as well as technical assistance, must be employed if the opioid epidemic is to be successfully addressed in the Communities. For example, hospitals, health systems, integrated delivery networks, physician practices, long-term care facilities, and other health care institutions and organizations should work diligently to incorporate educational programming and professional development services that assist in raising awareness and disseminating knowledge regarding the drivers of the opioid epidemic, as well as the role of their respective institutions in addressing it. In some instances, such programming may be delivered through Continuing Medical Education (CME), Continuing Nursing Education (CNE), or similar vehicles, although it is important that any such programming be scrupulously developed and monitored to minimize the potential for bias that might jeopardize the quality and impact of such materials.¹⁶¹ Locally, the OhioMHAS offers an online opioid curriculum focused on evidence-based practices surrounding addiction, prevention, screening, and MAT implementation across a broad range of clinical settings.¹⁶² Health systems play an especially important role given their broad reach and ability to promulgate evidence-based guidelines, as well as to engage in opioid stewardship.¹⁶³ Technical assistance to the courts, law enforcement, substance use treatment providers, and other stakeholders should also be provided so as to ensure that these entities are kept abreast of the changing contours of the epidemic and the most relevant advances in prevention, treatment, and recovery.
50. Components of abatement interventions. The top prescribers (physicians, dentists, nurse practitioners, and physician assistants) in the Lake and Trumbull Counties, as defined by prescribed opioid volume, should be the focus of a comprehensive academic detailing program. In each given year, prescribers who meet the inclusion criteria for being a top prescriber should be visited multiple times by preferably the same academic detailer. In addition to well-trained academic detailers, an effective academic detailing program should include experts who continuously develop and modify the detailing approach so as to be responsive to the clinicians they are visiting as well as to reflect the dynamic nature of the epidemic, advances in pain management and current clinical guidelines. Educational programming should also be aligned and coordinated with other types of provider outreach taking place within the Communities, such as the effort to expand SBIRT among Ohio health providers.¹⁶⁴ The program will also require administrative staff who will facilitate tasks as such scheduling and communication, travel itinerary, production/printing of modules, and other tasks. Moreover, CME and CNE programs should be provided to all prescribers in the Communities annually, building on the courses offered by OhioMHAS. Additional programs should also be developed to address the education and training needs of non-prescribers such as licensed practical nurses, pharmacists, and paramedics, although I have not included these quantitative estimates in my Redress Models.
51. In conclusion, abatement programs within the Communities should include health professional education. Efforts such as academic detailing are feasible and can be highly scaled as well; numerous state-wide and even national provider education programs promoting safe prescribing have been conducted during the past two decades, including across Pennsylvania (e.g., Department of Aging Pharmaceutical Assistance Contract for the Elderly [PACE] Academic Detailing Program),¹⁶⁵ Massachusetts (e.g., Boston Medical Center's Transforming Opioid Prescribing in Primary Care),¹⁶⁶ and the United States Department of Veterans Affairs (e.g., National Academic Detailing Service).¹⁶⁷ Many health systems, including large integrated delivery networks such as Kaiser Permanente,¹⁶⁸ have also executed such programs. Careful review of the evidence indicates that academic detailing works and would be an effective abatement tool for the Communities,¹⁶⁹ and it should be combined with broader health professional education as discussed above.

B. Patient and Public Education

The goal of this remedy is to raise awareness and activate patients and the general public in the Communities regarding the risks of opioids as well as the prevalence and treatability of OUD. Patient and public education can help to address the fact that many people do not understand the risks of opioids or that OUD is a treatable brain disease. It can also help to reduce stigma, which serves as a profound barrier to treatment.

52. Patient education is an important method of improving the safe use, storage, and disposal of opioids, since there are important shortcomings in patients' knowledge regarding these matters. For example, the 2016 CDC Guideline highlights the importance of clinicians discussing with patients the known risks and realistic benefits of opioid therapy before initiating treatment.¹⁷⁰ Other professional societies and organizations, such as the Veterans Administration/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain, also emphasize the importance of patient education as part of a multi-faceted strategy to maximize the risk/benefit value of opioids in clinical practice.¹⁷¹
53. In contrast to public education, which is addressed below, clinicians play an especially important role in educational outreach targeting patients who may be using opioids or otherwise at risk for opioid-related adverse events. However, clinicians themselves must be equipped to conduct such education, and their preparation for this can be maximized through academic detailing or other educational outreach as previously described. The Ohio Department of Health provides multiple resources for providers, such as the Opioid Pain Management Toolkit, with information on guidelines for prescribing opioids in multiple care settings.¹⁷² Additional educational materials have been developed by the CDC to promote safer opioid use and minimizing the risk of overdose;¹⁷³ SAMHSA's Opioid Overdose Prevention Toolkit includes a module providing safety advice for patients and family members;¹⁷⁴ and other organizations, such as the American College of Surgeons,¹⁷⁵ have developed their own messaging that can be used to educate patients regarding different aspects of the opioid epidemic.
54. Public education is also a crucial component in abating the epidemic, and one important way to conduct such education is through mass media campaigns. When properly designed and branded, such campaigns can deliver "sticky" messages, that is, messages that are concrete, memorable, contagious and therefore, impactful.¹⁷⁶ Such messaging can serve as part of an effective intervention to positively change health behavior.^{177,178} Despite this, not all mass media campaigns have been successful in achieving their desired impact,¹⁷⁹ and their success is dependent on several factors including the level and duration of investment made, the planning that goes into the campaign, and the availability of concurrent treatment and other services. A mass media campaign may include a variety of media, including television, radio, billboards, and social media. Though there is limited literature on mass media campaigns focusing on opioids, there is robust information from campaigns on alcohol, tobacco, and other illicit substances.
55. A number of these campaigns can be used as models when designing campaigns to address the opioid epidemic. For example, Idaho's Meth Project was aimed at reducing methamphetamine use through a comprehensive approach of public service announcements, community outreach, public policy approaches, and in-school lessons. Following the campaign's initiation in 2007, Idaho experienced a 56% decline in meth use amongst teens.¹⁸⁰ The U.S. Food and Drug Administration's (FDA) award-winning youth tobacco prevention campaign, "The Real Costs," is another example of a relatively recent mass media campaign. This campaign was launched nationally on multiple platforms, including TV, radio, print, and social media. The campaign was focused on reaching youths, 12 to 17 years old in the U.S., who were open to trying smoking or were already experimenting with smoking. In 2014-2016, high exposure to the campaign was associated with a 30% decrease in the risk of smoking initiation amongst youths.¹⁸¹

56. Several mass media campaigns addressing the opioid epidemic have been conducted nationwide.^{182,183} For example, in January 2017, then New Jersey Governor Chris Christie rolled out the ReachNJ initiative aimed at raising awareness about the availability of new addiction treatment services in New Jersey.¹⁸⁴ The initiative included television ads airing on New Jersey, New York, and Philadelphia television stations. As of January 2018, more than 18,600 people had called the ReachNJ hotline, with the frequency of calls at least three-times higher in April-June 2017, when television and radio ads were on air, compared to July-August, when only digital ads were used.¹⁸⁵ A second, 2017 CDC-funded program used video advertisements, radio advertisements, digital materials, and print materials to increase awareness and knowledge about the risks of prescription opioids.¹⁸⁶ Piloted in Ohio, Oregon, Rhode Island, and West Virginia, over 70% of individuals exposed to campaign materials correctly identified the campaign's message of preventing misuse of prescription opioid pain medications and over 50% linked this to the goal of preventing overdose deaths. A third example was designed to raise awareness about a new law increasing naloxone access and providing legal protection for people who call 911 to report an overdose. This state-wide media campaign in North Carolina focused on leveraging inexpensive platforms such as social media, printed flyers, public service announcements, and local media and was reported as effective in building connections with the local community and helping the organization become established as "the go-to expert for local media" regarding the epidemic.¹⁸⁷
57. Within Trumbull County, the Alliance for Substance Abuse Prevention (ASAP) Coalition conducts regular educational and prevention outreach in the community.¹⁸⁸ For example, the Coalition disseminates educational materials to address stigma, provides tools that parents can use to discuss substance use with their children, and maintains a directory of treatment and recovery supports within Trumbull County. In Lake County, Kim Fraser, the Executive Director of the Lake County Board of Alcohol, Drug Addiction and Mental Health Services, has conducted extensive outreach within the community to educate the public and address the drivers of stigma.¹⁸⁹ In addition to Ms. Fraser's work, the Lake-Geauga Recovery Centers administers the Education Program, which provides an 8-hour class to participants seeking to learn about addiction, prevention and recovery.¹⁹⁰ Topics covered include substance use, the disease concept, non-medical prescription drug use and the effects on substance use disorders on families.
58. Components of abatement interventions. A mass media campaign using platforms such as TV, radio, billboards, print, and social media should target all individuals aged 12 years and older who reside in the Communities, since they represent the population at risk. As per CDC guidelines, a minimum of 75% to 85% of the target population should be reached by the campaign.¹⁹¹ The mass media campaign should have a simple, effective message that has been developed by communication and content experts and that has been piloted and pretested using methods such as focus groups.
59. In conclusion, abatement programs within the Communities should include investments in educational campaigns targeting patients and the general public. Multimedia campaigns should include experts in health communications and public safety and be carefully designed to fully address widely prevalent yet insidious stigma that erodes effective community responses to the epidemic, treating addiction as a willful choice or moral failure, and cleaving off addiction and its treatment from other health care.¹⁹² These campaigns must also educate the general public both about the risks of opioids as well as the prevalence of OUD and its responsiveness to treatment. In addition, they should include messaging around the safe storage and disposal of opioids, since many individuals receiving opioids do not report having received such information.¹⁹³

C. Safe Storage and Drug Disposal

This remedy respects the principle of intervening comprehensively along the prescription opioid supply chain, including addressing enormous stockpiles of opioids in homes within the Communities, by providing individuals in the Communities with convenient opportunities to safely store and discard unused medicines.

60. Safe storage and drug disposal guidelines are a critical component of public education since the improper storage and disposal of unused prescription opioids is a widely recognized public health concern and an important component of the current opioid epidemic. Our own work suggests an increased risk of opioid initiation among household members of those prescribed opioids¹⁹⁴ – including an increased risk of opioid overdose among adolescents and young adults.¹⁹⁵ In a 2017 systematic review that my colleagues and I published in JAMA Surgery, 67-92% of surgical patients reported having unused opioids after surgery, and in two studies examining storage safety, 73-77% of patients did not store their opioids in locked containers, resulting in a large reservoir of opioids which contributes to the misuse of these products.¹⁹⁶ Other studies also support the assertion that the safe storage and proper disposal of opioids is uncommon.¹⁹⁷ The failure to safely store and dispose of unused opioids extends beyond surgical settings and contributes to the diversion of opioids as well as their non-medical use.¹⁹⁸ For example, of the 11.4 million individuals in the U.S. reporting opioid misuse in 2017, more than four in five (83%) reported that they bought, were given, or stole opioids from individuals who were in turn prescribed these drugs by a licensed prescriber.¹⁹⁹
61. Safe storage and drug disposal guidelines must be accompanied by increased availability of drug disposal programs, since these programs provide one avenue for proper disposal of unused opioids.²⁰⁰ Some disposal programs are based on periodic events. For example, the U.S. Drug Enforcement Administration (DEA) hosts short-term events wherein temporary collection sites are set up for the safe disposal of unused prescription medicines. Held on September 25, 2010, the DEA conducted the first-ever national drug take-back day, collecting over 121 tons of medications at more than 4,000 sites nationwide.²⁰¹ The DEA's most recent National Take Back Day was on October 24, 2020, and included the participation of 4,153 law enforcement personnel and 4,587 collection sites collecting a total of 492.7 tons of prescription drugs.²⁰² Since the inception of the semiannual National Take Back days, sites have collected a total of 6,842.4 tons of prescription drugs for safe disposal. During the most recent Take Back Day, 59,455 pounds of unwanted prescription drugs were collected across 266 sites in Ohio.²⁰³
62. Other disposal programs are based on permanent collection sites authorized by the DEA, such as within pharmacies or law enforcement facilities (**Figure 4, next page**). In Lake County, the Lake County General Health District and Lake County Solid Waste District administer the Pharmaceutical Drug Collection and Disposal Program.²⁰⁴ Across the County, there are seven permanent collection sites located at the: Eastlake Police Department; Lake County Sheriff Office; Lakeland Police Department; Madison Township Police Department; Mentor Police Department; Willoughby Hills Police Department; and Willoughby Police Department. In Trumbull County, the ASAP Coalition promotes information on disposal packets for safe at-home disposal and the location of permanent collection sites.²⁰⁵ Drug disposal packets are available at no cost across eleven sites in Trumbull County that include: public libraries; police departments; fire departments; health clinics; and recovery centers.²⁰⁶ Across Trumbull County, there are 15 permanent collection sites located in police departments and the St. Joseph Warren Hospital.²⁰⁷
63. Unless disposal programs are convenient, they are unlikely to be widely used, and the use of pharmacies as part of a “reverse logistics” program, where the standard distribution system is reversed to return unused or unwanted product, has many efficiencies.²⁰⁸ Some authorized collection sites may also provide mail-back options to assist patients in disposing unused medicines, especially for homebound patients or others with special needs. Local pharmacies may also provide free deactivation packets that individuals can use to deactivate their unused controlled substances before discarding them in the trash.



64. Although patients may favorably perceive drug disposal programs,²⁰⁹ historically, permanent collection sites have been uncommon due to administrative, legal, and economic barriers. As of 2017, the United States Government Accountability Office reported that only 2,233 of 89,550 eligible entities (2.5%), such as pharmacies, hospitals/clinics, narcotic treatment programs, reverse distributors, distributors, and manufacturers, were registered as authorized collectors of unused prescription drugs.²¹⁰
65. Despite their importance, historically, drug disposal programs have only re-collected a small proportion of the total number of controlled substances dispensed, with collected drugs also including a mix of other medications such as antibiotics, oral contraceptives, and cardiovascular treatments.²¹¹ Furthermore, the U.S. FDA directs that certain prescription medicines, such as opioids, should be immediately flushed down the toilet when no drug disposal program option is readily accessible.²¹² Patient and pharmacist education regarding how to properly dispose of opioids is important. In the absence of drug disposal programs, other routes of disposal include mixing unused opioids with inedible garbage (e.g., cat litter) or using specialized chemicals that trap the unused pills in a non-divertible and biodegradable matrix.²¹³
66. Components of abatement interventions. Existing efforts in Lake County and Trumbull County should be supported and promoted through varied means ranging from pharmacy posters or informational stickers on pill bottles to the promotion of drug disposal events to increasing the number of programs within pharmacies and health systems. Staffing needs will vary based on the magnitude of work involved. There are four major components to consider when establishing and maintaining a drug disposal program: (1) promotion; (2) staffing; (3) equipment and supplies; and (4) disposal.^{214,215} Equipment, supplies, and frequency of disposal will depend upon the volume of drugs collected, which can be estimated based on the population of the Communities. For context, prior studies of drug-take back initiatives based in pharmacies and police departments in rural counties report approximately 600 pounds of medications are collected a year.^{216,217}
67. In conclusion, abatement programs within the Communities should include investments to educate individuals regarding safe opioid storage and disposal, as well as to expand the availability and convenience of drug disposal programs. While periodic “take-back” days, such as those coordinated with the DEA, are impactful, such episodic programs should be complemented by accessible permanent collection sites that are continuously operated. In addition to placing take back kiosks within Police Departments, programs should be implemented throughout community pharmacies as well as urgent care centers, hospitals and health systems. For select populations, such as homebound elderly or others with special needs, it may also be helpful to invest in mail-back options and/or the distribution of biodegradable technologies that allow for safe and convenient at-home disposal.

D. Community Prevention and Resiliency

The goal of community prevention and resiliency programs is to form coalitions that can identify needs and trends within communities, and to implement evidence-based, culturally-responsive interventions that reflect the values, capacities and expressed needs of local communities. These programs seek to strengthen social bonds and promote healthy behaviors. In doing so, these programs bolster the resiliency of a community, in part by helping to mitigate the clinical, social and economic impact of the opioid epidemic in the Lake and Trumbull Counties.

68. Prevention science. The field of prevention science has flourished in the past few decades and it offers important lessons for the Communities. This is because a growing body of scientific evidence demonstrates that problematic behaviors of individuals, such as among adolescents, can be mitigated through prevention efforts. Through these scientific investigations, researchers have also identified risk and protective factors, which has allowed for rigorously-designed experimental evaluations of administratively feasible, community-based interventions.^{218,219,220} While many such interventions have focused on violence or delinquency, others have addressed substance use disorders and demonstrate enduring benefit.^{221,222}
69. Community coalitions. Many approaches to primary prevention of substance use disorder (SUD) have been proposed, including in Ohio. Some of the most promising are based on the use of community coalitions.^{223,224} The use of such coalitions provides one pragmatic and tested framework to identify community prevention needs, and to effectively implement durable, evidence-based interventions that command broad community support. Such efforts are designed to field durable, evidence-informed, and administratively feasible interventions that engage a diverse community coalition, and that effectively draw upon existing assets to meet the expressed needs of local communities.²²⁵ The broader community includes many entities that would be strong partners in such efforts, such as those from the business sector who may be key to implementing recovery-supportive workplaces (see Section 3C). Local nonprofits and government organizations, including the local Alcohol, Drug Addiction, and Mental Health Services (ADAMHS) boards, contain the local knowledge necessary to coordinate this effort in collaboration with outside researchers, community residents, and other stakeholders. This is similar to the objectives and efforts undertaken by Trumbull County's ASAP Coalition.
70. One prominent collaborative approach that coalitions can use to develop and implement effective programs is the Communities that Care (CTC) model. The CTC model, which has been used to prevent or reduce substance use, delinquency and/or other risk behaviors,²²⁶ provides a structure for engaging stakeholders and establishing a shared vision for the community. CTC provides tools to survey community members regarding pressing local needs and provides one well-studied process to pursue specific and measurable goals in partnership with experienced intervention researchers. Rather than being proscriptive, the CTC model provides local communities with a menu of evidence-based approaches, from which the coalitions can identify specific interventions and strategies in the formulation, and iterative evaluation, of a community action plan to address local needs.
71. CTC's effectiveness was tested in the Communities Youth Development Survey (CYDS), a randomized control trial of 24 urban and rural communities in seven states (Washington, Illinois, Kansas, Colorado, Maine, Oregon, and Utah).²²⁷ Outcomes by grade 12 were compared among youth who had received CTC interventions between fifth and ninth grade, and youth who resided in control communities. Youth within the CTC treatment group were significantly more likely to have refrained from any alcohol, tobacco, or other drug use, and were significantly less likely to have committed an act of delinquency.^{228,229,230,231,232,233,234} At an average inflation-adjusted cost of roughly \$633 per youth, CTC

has demonstrated cost-effectiveness, returning an estimated \$5.30 for every dollar invested through reduced crime and criminal justice costs and other benefits to local communities.^{235,236}

72. Components of abatement interventions. Community resiliency coalitions should be implemented, or continue to be supported, within Lake County and Trumbull County. These coalitions should build on the areas of need, identifying key stakeholders, evaluating and implementing evidence-based programs using a systematic and iterative process such as the CTC framework. There are five major components to consider when moving forward with a community prevention and resiliency plan: (1) staffing; (2) assembling pertinent stakeholder coalitions; (3) surveying community members to identify needs and assets; (4) formulating and implementing a community action plan; and (5) evaluating processes and outcomes associated with the community action plan. Staff devoted solely to the implementation and coordination of community prevention efforts will ensure efficiency and prevent duplication. These prevention programs should incorporate the data collected by a proposed team dedicated to reviewing and coordinating abatement programs and respond to the current and future needs of the community. Furthermore, a brick-and-mortar space dedicated to community prevention efforts, including stakeholder meetings, youth activities and prevention programs, may help to mitigate logistical barriers to implementing evidence-based programs that promote community resiliency.
73. In conclusion, abatement efforts in the Communities should encompass coalition building that focuses on promoting community resiliency. Programs that strengthen social bonds and promote health behaviors will help to heal the community-level trauma caused by the opioid epidemic. Frameworks such as CTC that incorporate measurable goals, are guided by local data and trends, and select evidence-based prevention programs have reduced substance use and reinforced social bonds within communities. A robust evidence base exists for the effectiveness and economic benefits of such efforts.

E. Harm Reduction

The goal of harm reduction is to implement evidence-based interventions that “meet people where they are at,” as compared to zero-tolerance approaches that criminalize opioid use, propagate stigma, and serve as a barrier to accessing treatment. Such approaches recognize the formidable barriers that often prevent people from seeking treatment or achieving full recovery; harm reduction will decrease individual and societal harms from the opioid epidemic in the Communities.

74. Harm reduction refers both to a set of general principles used to underpin policies concerning the way that societies respond to drug problems and to specific interventions. A defining feature of these approaches is their focus on harms associated with opioid use rather than the prevention of such use per se. Harm reduction approaches can target individuals as well as the structural (e.g., drug paraphernalia laws)²³⁷ and environmental (e.g., physical environment) contexts which engender harm.
75. Harm reduction can be contrasted with approaches that prioritize the singular prevention of drug use, which often are embodied in “zero tolerance” enforcement approaches.²³⁸ Empirical evidence has demonstrated short-comings of the U.S. “War on Drugs,”^{239,240} including its failure to reduce the demand for drugs^{241,242} or decrease drug-associated violence²⁴³ while leading to the disproportionate incarceration of people of color and the urban poor. Such findings underscore the need for innovative, evidence-based approaches to address OUD and other harms stemming from non-medical opioid use. An important component of any comprehensive response to the opioid epidemic includes scaled-up harm reduction services targeting people who are actively using drugs. There are two main harm reduction approaches that are relevant to the opioid epidemic and discussed below, syringe services programs and drug checking services; naloxone is discussed separately in Section 2E of this report.
76. Syringe services programs (SSPs) are designed to provide clean syringe access and disposal to people who inject drugs (PWID). Such programs were scaled up in the U.S., Europe, and Australia in the 1990’s and 2000’s to help reduce the transmission of blood-borne infectious diseases as discussed in Section 2C below. The U.S. Public Health Service has long recommended to have a clean syringe for every injection, effectively increasing the “coverage” of sterile injection equipment.²⁴⁴ Through extensive research over three decades, SSPs have been associated with reductions in risky syringe sharing behaviors,^{245,246,247} as well as rates of HIV,^{248,249,250,251} hepatitis B, and HCV.²⁵² A study by the National Institutes of Health found that syringe exchange programs are associated with a reduction in risk behaviors as high as 80% among injection drug users.²⁵³ A systematic review of SSP studies, including many from the U.S., found that SSPs are associated with a 32% reduction in the transmission of HIV and approximately a 50% reduction in HCV incidence among PWID.²⁵⁴
77. Unlike other states, Ohio law requires approval from county prosecutors prior to the implementation of an SSP.²⁵⁵ As of August 2019, there were 20 SSPs operating in Ohio.²⁵⁶ In 1995, the first SSP opened in Cleveland, Ohio, followed by another in Portsmouth in 2011 and Cincinnati in 2014.²⁵⁷ Since 2015, 17 additional SSPs have been implemented across Ohio, offering services that include: syringe exchange, wound care, HIV and HCV testing, chronic disease screening, fentanyl testing strips, and linkage to treatment for substance use disorder. The program in Lucas County also offers screening for human trafficking and food insecurity.²⁵⁸ Overall, Ohio SSPs report that the community and law enforcement response has been positive overall across counties that include, but are not limited to: Athens, Summit, Jefferson, Greene, Marion, Darke, Zanesville-Muskingum, and Lorain.²⁵⁹ Some communities and law enforcement agencies have shown mixed responses, or were slower to support the programs, however, many program leaders feel that additional education of the evidence-base and outreach within the communities would help to improve public opinion.

78. Mobile harm reduction programs are one tool to significantly improve access for hard-to-reach populations, including those that do not have access to transportation or who may reside in rural areas. Mobile SSPs are already in use in other Ohio locations, including an SSP in Dayton.²⁶⁰ A review of twelve HIV Outreach programs which included harm reduction services found that clients who accessed mobile units were 86-times more likely to receive an HIV test than those who accessed other sites.²⁶¹ The authors noted that mobile outreach increased recognition and opportunities to initiate conversations with new clients and such outreach may increase the likelihood that an individual will enter treatment.
79. SSPs also save communities money in the long term by preventing disease transmission, reducing overdose and injury associated with drug use, and increasing the likelihood of linking individuals with substance use disorder treatment.^{262,263} This is because SSPs generally include onsite evaluation and referrals for substance use disorder treatment for an otherwise difficult to access population. As of October 2017, there were an estimated 310 SSPs in 42 U.S. states and Washington, D.C.²⁶⁴ Despite anecdotes to the contrary,²⁶⁵ SSPs do not increase illegal drug use or crime. For example, analyses of such programs in New York City and Baltimore indicate no difference in crime rates between areas with and areas without SSPs, including trends in arrests and violent crimes.^{266,267}
80. SSPs often provide medical services for PWID, many of whom are marginalized and may have otherwise very limited access to ambulatory care. In addition to doctors, nurses, and social workers, such care may include peer recovery coaches, whose potential value and services are discussed in Section 2A. Clinical services delivered as part of SSPs may include care for acute conditions such as upper respiratory infections, chronic conditions such as diabetes or cardiovascular diseases, or most commonly, preventive screening and other preventive interventions such as flu shots or other vaccinations. Such programs may also include family planning services. Individuals who test positive for HIV, HCV, or both should be referred for treatment. Positively identified individuals will require access to necessary health care including effective antiretrovirals and direct-acting antiviral treatments that treat HIV and HCV, respectively, as well as treatment for their underlying OUD, including access to MAT and other treatments for opioid use disorder.
81. Drug checking services enable people who use drugs to have the content of their drugs chemically analyzed, allowing them to make informed decisions about use.^{268,269} Drug checking, a method pioneered in Europe, has the potential to introduce the concept of product safety into the unregulated illicit drug supply in the U.S. Currently, its use in the U.S. has been limited to raves or similar parties, primarily for the testing of 3,4-methylenedioxy-methamphetamine (MDMA, or “ecstasy”). Recently, some U.S. SSPs have begun distributing fentanyl testing strips originally designed for testing urine samples. Such “fentanyl checking” allows users to objectively determine whether their drug samples contain fentanyl or fentanyl analogues. Though some may argue that the widespread prevalence of fentanyl decreases the utility of drug checking machines or fentanyl testing strips, there remain key reasons to support testing: (1) drug supply and composition is not consistent over time and circumstances may change in the Communities; (2) testing serves as a reminder for intravenous drug use (IVDU) hygiene, including acquiring extra doses of naloxone or consuming drugs with a friend present; and (3) it can identify counterfeit pills. This is important in part because the drug market is unstable and prone to dramatic fluctuations in product composition.²⁷⁰ As such, drug check machines allow individuals to check for other cutting agents that may cause injury or death.
82. In 2019, 1,070 Ohioans died of an unintentional overdose that involved fentanyl, representing 76% of all unintentional drug overdose deaths.²⁷¹ Given that 83.7% of 2019 Ohio overdose deaths involved an opioid, fentanyl is responsible for a significant mortality. During the same year, nine out of ten people who died of a drug overdose in Trumbull County had fentanyl in their system.²⁷² While few evaluations of fentanyl testing services have been performed, recent assessments suggest a high degree of acceptability and

potential utility among PWID,^{273,274,275} and early evidence suggests checking for fentanyl in drug samples at SSPs, police departments, and other relevant sites may help guide appropriate responses to the changing nature of the opioid epidemic. For example, a study conducted in Greensboro, North Carolina, found that 43% of people who inject drugs reported a change in drug use behavior and 77% indicated increased perceived overdose safety by using fentanyl test strips.²⁷⁶ At a harm reduction site in British Columbia, Canada, 36% of participants reported planning to reduce their drug dose while 11% planned to dispose of their drug after testing for fentanyl.²⁷⁷ These findings were mirrored in a study of PWID in Baltimore, Boston, and Providence, which found that over half of respondents would utilize fentanyl testing every day.²⁷⁸ In Dayton, Ohio, a survey of SSP clients found that one in five did not use their drug supply after it tested positive for fentanyl, and of those who used the drug differently, two in three reported that they used a lesser quantity.²⁷⁹

83. Despite these positive impacts on the health of Ohioans, positive response from many of the local communities and law enforcement agencies, and the substantial evidence-base to support SSPs, harm reduction services are underutilized both in the Communities and Ohio overall.²⁸⁰ Important barriers to scaling up these services in the Communities including insufficient funding as well as the absence of broad community support, which in turn is driven in part by pervasive stigma.²⁸¹ In addition to providing preventive services that reduce the burden of disease, such as skin and soft tissue infections, HIV, HCV, and chronic diseases, and offering a source for individuals to be linked to treatment, harm reduction programs can also reduce stigma by providing education to the community.²⁸² It is important to note that there is no evidence to support that harm reduction services (e.g., SSPs) encourage and enable drug use.²⁸³
84. Components of abatement interventions. Leaders of Lake and Trumbull Counties should consider investing in harm reduction services to provide access to clean syringes and injection equipment, safe disposal of used syringes, and screening and referral services to PWID, particularly for those who use heroin and fentanyl. SSPs should provide continuous services at consistent locations and hours using different approaches including permanent SSP sites and mobile SSP units, generally vans. Investment in establishing or expanding fentanyl testing services is also needed to mitigate some of the risks – including overdose and death – associated with fentanyl use or fentanyl laced drugs. Two main channels of fentanyl testing services should be considered: fentanyl test strips and drug checking machines. Fentanyl test strips should be available for use or distribution at SSPs, homeless shelters, and other relevant locations to achieve optimal coverage and reduction in harm. Given their low cost, fentanyl testing strips should be distributed to all individuals that use illicit substances in the Communities. Drug checking machines, such as Fourier transform infrared spectrometers (FTIRs), are needed to track and document changes in the illicit drug supply to inform timely responses by health officials and law enforcement. At minimum, SSPs, police departments, and medical examiners may all benefit from the use of such drug checking machines.
85. In conclusion, abatement programs in the Communities should include resources to further support harm reduction. Given the success of SSPs in Ohio, the substantial evidence base in promoting public health, and established cost-effectiveness in preventing the spread of disease and linking individuals to treatment, SSPs should be implemented in Lake County and Trumbull County. SSPs, including outreach, delivery of non-OD care, and referral for treatment, should be expanded sufficiently so as to reach the broadest population of individuals who inject drugs in the Communities. Such programs should include increased availability of drug checking services to assist users in knowing when fentanyl may be present within drug supplies. It is also crucial that outreach, advertising, and education be incorporated into the SSPs in order to reach clients and provide awareness in the Communities.

F. Surveillance, Evaluation, and Leadership

The goal of surveillance is to convert local data to actionable intelligence at a local level by gathering, curating, and disseminating timely information about key dimensions of the epidemic to public health officials, policy-makers, and other stakeholders. This is important because the absence of timely, granular information about the epidemiology of opioid use, addiction, and overdose at a local level has limited the ability of stakeholders to rapidly design, iterate and evaluate targeted interventions to address the epidemic in the Communities. However, in addition to surveillance, leadership – including comprehensive planning and multi-agency coordination – is important in order to maximize efficient use of constrained resources to address the epidemic.

86. The opioid epidemic is a complex phenomenon with many different dimensions and impacts, and while it continues to change and evolve at a national and state level, at a local level these changes have often been even more profound. One consequence of this is that policy-makers and public health officials such as those leading the Communities need timely and accurate information on key parameters they can use to make informed decisions about resource allocation.²⁸⁴ For example, the deployment, targeting and evaluation of academic detailing programs depends vitally on timely information regarding opioid prescribing across prescribers. Similarly, naloxone distribution and training should be designed based on the relative incidence, causes and outcomes of overdose within small, well-defined geographic areas.
87. These methods of assessing the opioid epidemic are important and should be expanded to include other important dimensions of the crisis including measures that allow for near real-time, integrated assessment of prevention, treatment, and recovery within the Communities. Such data can be drawn from medical, behavioral and criminal justice systems, and include, but not be limited to, measures such as: opioid and non-opioid analgesic prescribing, OUD treatment capacity, MAT use and persistence, non-fatal and fatal opioid overdose events, naloxone distribution and use, criminal justice offense type, sentencing, treatment received while under court supervision (e.g., mandated treatment) and reoffending rates. Valuable information – relevant to the Communities – can be compiled from national, state and local levels. For example, clinical information can be derived from OARRS, emergency medical services, and hospital and emergency administration data. The Ohio Department of Health publishes the drug overdose data, NAS trends, and ED visits for suspected drug overdoses.²⁸⁵ Additionally, since 2000, the OSAM Network has published semiannual reports on substance use trends across eight subregions in Ohio and Targeted Response Initiatives to help guide additional interventions.²⁸⁶ These reports are generated through focus groups and qualitative interviews of individuals affected by the opioid epidemic: people who actively use drugs, those who are in recovery, family members of those with OUD, and community professionals that work to address OUD. Behavioral health data can be drawn from sources such as the minimum data sets that are directly collected by all Single State Authorities (e.g., state agencies on drug abuse) for specialty treatment programs and from Medicaid programs, as well as from sources such as the Drug Enforcement Agency's National Technical Information Service (NTIS) database of waived prescribers and state and federal databases on specialty treatment providers (e.g., the SAMHSA treatment locator which is updated annually and provides street addresses for treatment programs). Criminal justice data can be derived from the Ohio Department of Rehabilitation and Corrections.
88. There is no question that the collection, curation, and integration of these data will require substantial cooperation, effort, and tenacity. Many of these data systems are maintained by different private or public entities, and in some cases, significant administrative, legal, and cultural barriers will have to be overcome. However, there is tremendous promise in such efforts, especially since the effects of the opioid epidemic, and remedies to abate it, extend across medical, behavioral, and criminal justice systems. Linkage of these data will provide a more comprehensive understanding of the current issues associated with the epidemic and identify areas where local communities should focus.

89. For example, consider the case of policing, where public health oriented policing interventions, such as a focus on overdose deaths, use of naloxone, education regarding addiction and stigma, and treatment on demand, can play an important role in reducing opioid-related injuries and overdose deaths.²⁸⁷ Routine tracking of measures that evaluate these and other approaches can be used for a number of purposes including to establish benchmarks, allocate resources, and evaluate the success of new initiatives with respect to process, such as how many doses of naloxone have been dispensed, and outcomes, such as how many overdoses have been reversed. Medical examiner data is another important source of information to be incorporated into any surveillance system. However, medical examiners must work within the constraints of their operating budget, and as observed in the Communities,²⁸⁸ the increasing number of overdose deaths has strained medical examiner offices.
90. Surveillance must be combined with leadership and a cohesive, multidisciplinary team should coordinate a given community's response across multiple agencies, departments and stakeholders and be based on a comprehensive needs assessment. Representation, and appropriate staffing, from key entities such as the medical, behavioral and criminal justice systems within the community is vital. The overall effectiveness of a community's response will rest in part upon the relationships among those coordinating the effort, and the overall coherence and shared vision among relevant parties. This team should meet regularly to review programs and policies, as well as assess surveillance data and emerging evidence from the field. In addition to serving as liaisons to their respective organizations, as well as more broadly championing the community's strategic response, the team should troubleshoot, redirecting resources and re-engineering how individuals with chronic pain, non-medical opioid use or OUD are identified and managed within relevant systems of care.
91. Components of abatement interventions. Abatement efforts in Lake County and Trumbull County should build upon the current surveillance and data sources, such as OSAM drug trend reports, by allocating sufficient resources to support a dedicated team of professionals to review and synthesize data, and to make recommendations for abatement efforts. This team, may include individuals such as epidemiologists, data scientists, and community liaisons, such as law enforcement experts and community advocates, should focus on: (1) improving the timeliness, quality, coordination and integration of existing data streams (e.g., surveys, mortality records, etc.); (2) conducting opioid-specific surveillance activities to better understand key aspects of the dynamic nature of the epidemic that are not visible through existing data channels; (3) enhancing the accessibility, visibility, and shareability of data related to the epidemic through multi-agency coordination, preparation of reports and data summaries, creation of dashboards, and responses to data requests from relevant stakeholders; and (4) performing comprehensive evaluations of interventions and proposing evidence-based recommendations so as to maximize further returns. Given their role in surveillance systems, medical examiners should also be supported in the Communities so as to alleviate the strain caused by the increasing number of deaths and reduce the turnaround time for toxicology testing. Quality surveillance data and dissemination is key to identifying and responding to changing needs within the Communities.
92. In conclusion, abatement programs in the Communities should include resources to support the further development and management of state-of-the-art surveillance programs that can serve as mission control centers as remedies are deployed, iteratively refined and evaluated. Such resources should allow for relevant data from a variety of local, state, and national sources to be gathered, curated, integrated and analyzed, and in turn, reported back out using a variety of different approaches customized to the specific needs of key stakeholders such as public health officers, treatment providers, and law enforcement officials. Remedies should also include resources to support the leadership that will be needed for a well-coordinated, longitudinal, multi-stakeholder initiative.

CATEGORY 2: TREATMENT – SUPPORTING INDIVIDUALS AFFECTED BY THE EPIDEMIC

This category of my Abatement Plan seeks to better identify individuals with OUD in the Communities and to remove clinical, economic, and social barriers diminishing their access to comprehensive, coordinated high-quality care.^m One important principle is to close treatment gaps. However, many other interventions are necessary in addition to the closure of treatment gaps, including a transformation of the delivery system of care in the Communities so that it “mainstreams” addiction care and delivers it as consistently and compassionately as it does care for pediatric cancer or amyotrophic lateral sclerosis (ALS).

A. Connecting Individuals to Services and Care

The goal of this remedy is to address the widespread treatment gaps that prevent so many from seeking or being retained in care. For example, studies show that some individuals who overdose in the field are not formally evaluated or successfully linked with treatment,^{289,290} while many others, even if brought to an Emergency Department are discharged rather than transferred to an inpatient induction/rehabilitation facility, enrolled in an intensive outpatient (IOP) program or initiated on MAT.²⁹¹ There are opportunities to improve the identification and treatment of individuals with OUD within each of these settings. Because of this, multiple methods are needed to connect people to services, ranging from helplines, peer-recovery coaches and transportation assistance to “bridge programs” and Quick Response Teams designed for those newly encountering the health care system due to an opioid overdose or other acute opioid-related harm.ⁿ

93. Helplines. Helplines have been used as an effective tool for delivering information to people in crisis for decades, assisting callers by linking individuals to care and resources to address their individual circumstance. Helplines serve as an inexpensive, efficient, and immediate source of information for individuals affected by SUD. The Lake County Alcohol, Drug Addiction, and Mental Health Services (ADAMHS) offers the Compass Line, which is designed to streamline access to treatment.²⁹² Between 2012 and 2018, the Compass Line made over 8,000 referrals to behavioral health resources.²⁹³ Ideally, helplines should be a 24-hour phone, text, and chat line designed to streamline the process of accessing treatment for SUD and behavioral health. Staff should be comprised of social workers that provide direct transfers to withdrawal management facilities and referrals to inpatient treatment, sober living homes, medications for addiction treatment, outpatient therapy and support groups. After linking callers to resources, staff should follow up with callers at designated intervals to ensure their needs are being met. Since 2015, one such helpline in West Virginia has helped more than 41,000 individuals access treatment.²⁹⁴ In 2019, more than 11,000 individuals called the helpline, of which 75% called on behalf of themselves and 13% called on behalf of a family member. Opioids were the most commonly used substance among helpline callers (40%). Over 14,000 callers have received a “warm hand-off” to a service provider,²⁹⁵ nearly 2% were referred to MAT, and 43% were referred to detoxification centers; of those seeking detoxification, many were able to enter a program within 24-hours.²⁹⁶ Staff are also available to assist callers with enrolling in Medicaid or private health insurance. The helpline is one tool to address barriers for those with OUD in finding treatment, timely linkage and entry into treatment. Importantly, the helpline is another source of data for policy-makers to identify trends in drug use, treatment needs and capacity building.
94. Coaches. Peer recovery coaches provide another promising and cost-effective model to engage and serve individuals with OUD.^{297,298} Paraprofessionals with lived experience in recovery can assist patients in accessing medication treatment, can help navigate barriers to treatment engagement and retention, such

^m It is also important to consider individuals with opioid dependence and non-medical use who may not yet fulfil formal criteria for an OUD; I consider these individuals in Section 4E.

ⁿ Ensuring adequate staffing of social workers, case managers, and addiction counselors in clinical, behavioral, criminal justice, and community settings is also vital and discussed elsewhere in my report

as provider stigma and transportation. Peer recovery coaches can draw upon their lived-experience and methods such as motivational interviewing to strengthen individuals' motivation to seek treatment and to remain engaged. Coaches may provide a number of different types of resources or support to individuals with OUD, ranging from psychological support to connections to recovery communities, activities, and events.²⁹⁹ Two systematic reviews examining the impact of peer-recovery services suggest the positive impact that such services can have on those with substance use disorders.^{300,301} Peer recovery coaches should be integrated into programs and organizations within the Communities, including the Ohio Criminal Justice System and Harm Reduction Programs. Further expansion and integration of peer recovery coaches into programs, such as reentry programs and drug courts, are important in order to connect individuals with OUD to services and treatment in the Communities. The OhioMHAS currently offers a 40-hour training and certification for peer recovery coaches.³⁰²

95. Medical Social Workers. Medical social workers address the psychosocial needs of an individual, such as housing or transportation, that increase the likelihood of continuing treatment and recovery. Within the Communities, social workers should be integrated within the continuum of medical care for OUD to alleviate community resources and ensure wrap-around care. The intensity of social work intervention will vary based on the needs of the population and duration that they have been in care. For example, pregnant women who are newly linked to treatment will require more intensive social work and case management services, which can be tapered down after two-years in care (see Section 4A). Additionally, social workers are also effective in services for families and children (Section 4C), homeless individuals and those who are housing insecure (Section 4D), reentry and reintegration programs (Section 3B), and for individuals newly entering OUD treatment (Section 2B). Expanding case management to these populations would ensure that individuals will not “fall through the cracks,” improving treatment and recovery outcomes.
96. As health care has become more specialized and fragmented, social workers are also needed to coordinate care and facilitate communication between members of the health team. This is important both for the treatment of OUD and for preventing opioid misuse among patients treated for pain. In addition to ensuring smooth transitions between different levels of care, case managers can assist clients in setting treatment goals. One community-based, behavioral intervention trial found that compared to passive referral, individuals who received case management were 50% more likely to engage in treatment with MAT within seven days.³⁰³
97. Transportation. Transportation, particularly in rural communities, represents a significant barrier for those with OUD to access and adhere to treatment.³⁰⁴ Because of this, the Lake County ADAMHS Board offers a transportation call line that helps individuals who rely on public transportation get to their ADAMHS system behavioral health appointments.³⁰⁵ Though public transportation may be available within cities, those that live outside urban centers may not have consistent or reliable transportation needed to attend treatment, thereby reducing the likelihood that they will be able to adhere to treatment.³⁰⁶ However, transportation needs remain for other individuals as well, such as those accessing harm reduction services or for pre- and post-natal appointments for women with OUD. Providing travel vouchers, reimbursing taxi or ride-sharing costs, or providing gas cards are additional options to improve access to such services.³⁰⁷
98. Emergency Department Bridges. The Emergency Department represent a key setting to link individuals to treatment after an overdose. One randomized control trial found that patients who received ED-initiated MAT were two-times more likely to be engaged in treatment one-month after intervention, compared to patients that received a Brief Negotiation Interview or referral alone (78% vs 37-45%, respectively).³⁰⁸ While patients in all three intervention groups reported lower HIV risk behaviors, those that received ED-initiated MAT had lower self-reported opioid use one-month after baseline. In reviewing the response to the outbreak of 26 opioid-overdoses within a six-hour window in the City of Huntington, West Virginia

in August 2016, public health officials recognized that failing to link individuals to treatment during their ED visit was a missed opportunity and break in the continuum of care.³⁰⁹ In nearby Mahoning County, local EDs have also initiated bridge programs to decrease the time between overdose and initiation of treatment.³¹⁰ Adequate expansions in infrastructure are needed to increase treatment capacity to meet current demand as well as to accommodate individuals who will be connected to care through an increasing number of initiatives.

99. Quick Response Teams (QRTs). Sometimes known as a Drug Abuse Response Team (DART), these teams generally consist of a first responder, addiction counselor, and peer recovery coach, and they are designed both for first response to narcotic-related emergencies, as well as to approach overdose victims during “recovery windows,” a 48- to 72-hour period following an overdose when individuals may be most amenable to entering treatment. These teams are similar to rapid-response, mental health evaluation teams; QRT’s or DART’s are focused specifically on overdoses or other opioid-related emergencies. A QRT includes addiction counselors and target individuals who may have had a recent overdose but who are not experiencing an active emergency.³¹¹ In Trumbull County, the Newton Falls Police Department implemented a QRT in addition to their Safe Passages program, wherein both programs seek to link individuals to treatment.³¹² In the same year, Lake County also established a QRT, comprised of a law enforcement professional, paramedic or firefighter, and behavioral health professional.³¹³ Other QRTs in the region have included a paramedic, peer recovery coach and social worker or member from the faith-based community.³¹⁴ Following referrals from EMS or family and friends, the QRT seeks to make contact with the individual, and if they accept treatment, the QRT arranges for them to quickly enter treatment. If the QRT is unable to make contact, they leave treatment information behind. The Lake County QRT reports that 30% of those who the QRT has attempted to contact have accepted treatment or are already in treatment.³¹⁵ This QRT is composed of professionals from the Lake County Sheriff’s Office; Lake County Alcohol; Drug Addiction and Mental Health Services Board; Signature Health; the Perry Joint Fire District; Perry Village Police Department; and Concord Township Fire Department.^{316,317,318} Because of their timely response as well as multidisciplinary composition, these teams are one means of helping to strengthen the community-individual relationship as well as to bridge one treatment gap that prevents many individuals with OUD from seeking care.
100. Components of abatement interventions. A 24-hour helpline, with text, chat, and voice capability should be available in Lake and Trumbull Counties. In addition to their use in clinical settings, peer recovery coaches should be incorporated in locations where they are highly likely to interact with individuals with OUD such as drug courts, reentry programs, recovery houses, and opioid treatment programs. April Caraway reports³¹⁹ that efforts, such as Bridge programs in EDs, should be expanded in the Communities in order to reduce the time that an individual enters into treatment and initiate MAT. Transportation for services including and adjacent to OUD treatment should be provided. Finally, given the success and positive response to QRTs, they should be adequately staffed and resourced proportional to the burden of non-fatal overdoses. Each QRT should consist of an addiction counselor, first responder, and peer recovery coach. QRTs should be rapidly notified of overdoses in a timely manner so as not to miss the window when they are most effective; QRTs also must have access to and maintain a follow-up database to keep track of individuals connected to care.
101. In conclusion, abatement programs in the Communities must support both the linkage of individuals to care and their retention once in treatment and recovery. Helplines, QRTs, peer recovery coaches, transportation initiatives and Bridge programs are effective and established tools to link individuals to treatment. Since people who use drugs may be difficult to reach, efforts that build rapport and maximize the quality of interactions are crucial. There are also key reachable moments, such as during hospitalization and “recovery windows” following an overdose, when people who use drugs may be most amenable to initiating treatment. Retention in treatment must be supported by transportation assistance

and other measures to increase access, ensuring smooth transitions across the continuum of care and through peer-support.

B. Treatment for Opioid Use Disorder

Though there have been efforts to scale up treatment within the Communities for those with OUD, more investments are needed so as to fulfill the overarching goal of this remedy: the provision of readily accessible treatment to patients with OUD. Such treatment should include access to FDA-approved MAT for use in individuals with OUD, since these are efficacious treatments that not only reduce the likelihood of opioid use, but also the risk of overdose, criminal activity, and the transmission of infectious disease.³²⁰ However, not everyone with OUD requires MAT, and even when it is provided, it should be part of a full continuum of care, including care that addresses other acute, chronic, and preventive needs.

102. The FDA has approved three medications for the treatment of OUD and the choice of medication should be tailored to the unique needs of each individual.

- 1) Methadone is an opioid agonist, which means it can activate opioid receptors in the brain and provide pain relief similar to other opioids. It can prevent withdrawal symptoms, reduce cravings and block the euphoric effects of other opioids. However, due to federal regulations, its dispensing for OUD is limited to certified opioid treatment programs, serving as a barrier to broader use.³²¹
- 2) Naltrexone is an opioid antagonist that blocks the effects of other narcotics. Provided as a daily pill or monthly intramuscular injection, it can be prescribed in ambulatory settings and does not have any abuse or diversion potential.³²² However, it cannot be administered to individuals with opioids in their systems, since doing so will precipitate abrupt opioid withdrawal.³²³
- 3) Buprenorphine is a partial agonist and partial antagonist of the opioid receptor, with significantly lower potential to produce euphoria or respiratory depression than other opioids. Appropriately waived physicians may prescribe buprenorphine in offices, community hospitals, or correctional facilities.³²⁴ While the main form of buprenorphine for OUD is an orally administered combination of buprenorphine and naloxone (the latter of which is an opioid reversal agent as described in Section 2E), other formulations of buprenorphine are likely to be FDA approved in the years to come.³²⁵

103. Historically, some have opposed MAT based on a number of misconceptions, including that it is invariably diverted (it is not, and when diversion does occur, it is often to avoid the dysphoria of opioid withdrawal including symptoms such as agitation, anxiety, muscle aches, nausea, and vomiting),^o or that it is simply substituting one addiction for another (it is not).³²⁶ Rather, MAT increases social functioning and retention in treatment, allowing individuals a better opportunity to reintegrate within their families and communities and to transition from active addiction through treatment into recovery.^{327,328} It is also associated with a wealth of other positive outcomes, including decreased opioid use and improved survival.³²⁹ Because of this, its use is supported by numerous authoritative sources, including the CDC, National Institutes of Drug Abuse, American Society of Addiction Medicine, and SAMHSA. It is also supported by global authorities such as the World Health Organization, which includes buprenorphine and methadone as Essential Medicines.³³⁰ However, as I discuss further in Paragraph #108, MAT is not a stand-alone therapy nor does everyone require it; when it is used, it must be accompanied by other clinical interventions as part of comprehensive care for those with OUD.

104. Despite the potential of MAT to help address the opioid epidemic, it is severely underutilized. For example, an analysis of 2012-2013 data from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) indicated that fewer than one in five individuals with non-medical prescription

^o Even the need for such defense of MAT underscores the marked stigma and asymmetry that exists between OUD and other diseases; for example, it is hard to imagine a setting where the use of inhalers for asthma, insulin for diabetes, or even psychotropics for mental illness, would be met with such skepticism or outright opposition.

OUD were ever treated,³³¹ and rates of use of MAT within publicly funded treatment programs have historically been low.^{332,333} Combined with low use of MAT even within programs offering it, some estimates are that as few as one in ten individuals with OUD receive MAT.³³⁴ Worsening matters further, treatment courses are often short, with rates of treatment discontinuation and relapse high,³³⁵ and even periods of MAT use are often punctuated by the receipt of prescriptions for non-MAT opioids, underscoring common and serious lapses in care even for those accessing these treatments.^{336,337} The situation is further complicated in the Communities, where there is a lack of public transportation for individuals who live outside of more urban areas.

105. A 2018 study from Massachusetts provides useful context for the benefits of MAT in decreasing mortality.³³⁸ In this analysis of adults who survived an overdose between 2012 and 2014, in the 12 months after an overdose, 11% received methadone, 17% received buprenorphine, and 6% received naltrexone. The median duration of treatment was short, between one to five months. Both methadone and buprenorphine utilization were associated with decreased opioid-related and all-cause mortality.^p Thus, this study underscores: (a) large gaps in MAT adoption; (b) high discontinuation rates; and (c) the life-saving benefit of methadone and buprenorphine.
106. There are many barriers that account for the large gap between the number of individuals with OUD and the proportion that are treated with MAT. Underlying these barriers are misconceptions about the nature of OUD and the effectiveness of MAT, as well as other concerns such as those identified in Paragraph #103. In a 2019 study based on national surveys, my colleagues at the Johns Hopkins Bloomberg School of Public Health found that only about one in three substance use treatment facilities offered MAT in 2016, and fewer than one in sixteen (6.1%) offered all three treatment medications.³³⁹ There is also a large shortage in the number of providers who are equipped to provide care for those with addiction.^{340,341} Finally, the costs of MAT, as well as other treatments for OUD, have historically been an impediment for many individuals who might otherwise seek care.³⁴² While our own work,^{343,344} and that of others,³⁴⁵ suggests that health plans are increasingly modifying their coverage and reimbursement policies so as to address the opioid epidemic, many individuals with OUD still face economic barriers to treatment, with a 2016 Department of Defense estimate of the costs of MAT³⁴⁶ exceeding that of diabetes mellitus (\$3,560) or kidney disease (\$5,624).³⁴⁷
107. Overcoming these economic and structural barriers is just the first step in achieving the potential for high quality OUD care.³⁴⁸ This is because there is enormous stigma associated with opioid addiction, which discourages patients from seeking treatment and discourages clinicians from providing it (also see Paragraph #106).³⁴⁹ While OUD is a brain disease, it is often framed as a moral failing instead; treatment systems remain marginalized rather than “mainstreamed”; language about “legitimate pain” and “junkies” and “getting clean” perpetuates such marginalization; and many features of the criminal justice system’s intersection with OUD also contribute to the persistent organizational failures that are seen.³⁵⁰
108. Investments in the treatment infrastructure must be made along a full continuum of care, from overdose reversal to support that enables long-term recovery. Individuals with OUD need regular contact with health care professionals responsible for supervising their pharmacologic and/or behavioral treatments, screening for adverse events or treatment failures, and delivering supportive care and psychological counselling. In many ways, such a model is no different than a model of care for someone with asthma or diabetes. These diseases, and their treatments, cannot be managed in a vacuum. Medications, whether MAT or treatments for other chronic diseases, should be provided in the context of a therapeutic

^p The authors speculated several reasons they may not have observed a statistically significant benefit with naltrexone, including a small sample and short duration of use, with most patients receiving it for a single month. In addition, the study was unable to differentiate oral from intramuscular naltrexone.

relationship where risk factor attenuation, supportive counseling, medication monitoring, and attention to other health care needs take place. In the case of OUD, the delivery of structured social support and counseling may be especially important, given that these engagements assist patients in establishing the social reconnection that can be critical to long-term recovery. Treatment must also recognize the importance of screening and treatment for infectious diseases such as hepatitis C and HIV,³⁵¹ as well as attending to chronic pain, other substance use disorders, and mental illness, all of which are common among individuals with non-medical opioid use or OUD.³⁵²

109. In addition, no single treatment is right for everyone, and not every individual with a history of OUD should be treated with MAT. For example, some people have a remote history of OUD and while they retain a lifelong sensitivity and vulnerability to opioids, just as an alcoholic does to alcohol, many of these individuals are living productive, successful lives in recovery without MAT. Some individuals have been treated with MAT but successfully tapered off of such treatment while maintaining a healthy recovery through abstinence-based, 12-step programs such as Narcotics Anonymous, psychological counselling, and supportive therapy, or combinations of these or other approaches. The 12-step program has deep roots in the Communities given their proximity to Akron, OH, the birthplace of the 12-step program.³⁵³
110. There are many different models for expanding access to OUD treatment within the Communities, and this remains an area of rapid growth and program evaluation nationwide. For example, Office-Based Opioid Treatment (OBOT) allows for physicians completing a waiver program to prescribe buprenorphine for OUD within primary care settings; the Medicaid Health Home Model integrates MAT and behavioral health treatments with primary care for people with OUD; and the Hub-and-Spoke Model triages patients between primary care clinics for the treatment of uncomplicated OUD (the “spokes”) and centralized clinics equipped to care for patients requiring methadone or whose complex behavioral and medical needs exceed those routinely provided in primary care settings (the “hub”).³⁵⁴ Other models are based on ED Bridge Programs as described in Section 2A.³⁵⁵
111. Models that rely more heavily on telemedicine for MAT supervision are also increasingly common, given the ongoing COVID-19 pandemic. For example, my colleagues and I estimated a 7,360% increase in the prevalence of telemedicine visits for OUD from April to June of 2020 compared to the same timeframe in 2019.³⁵⁶ Beyond the pandemic, telemedicine may increase the accessibility of MAT and treatment retention by overcoming transportation barriers as well as making MAT more available in settings where there are shortages of health care providers. Of course, despite the potential benefits of telemedicine, there are several reasons that it may not be a suitable means of clinical care for particular individuals, such as those uncomfortable with the technology or with complex comorbid illness where face-to-face evaluation may be especially important.
112. Treatment programs differ along many dimensions, such as the degree to which they focus on the delivery of pharmacotherapy, behavioral services, care integration, and community-based education or outreach. It is important that some programs are designed to deliver care to individuals who have initiated MAT, or “induction,” in low-barrier settings such as syringe services programs or EDs, given that the marginalization and social isolation of some of these individuals increase their likelihood for relapse or treatment discontinuation. The optimal program for a given city or county will depend upon a variety of different factors including the adequacy of the primary care and specialty workforce, urbanicity, and existing infrastructure devoted to addiction treatment.
113. Most individuals with OUD who are entering treatment can be managed either in an ambulatory or intensive outpatient (IOP) setting, although initial evaluation and appropriate triage is important so as to optimize each individual’s likelihood of successful treatment and recovery. IOP programs typically provide for several hours of patient engagement four to five days per week for a period of several weeks,

and may include services ranging from individual, group and/or family counseling to case management to vocational training and employment services.³⁵⁷ A minority of individuals with OUD require inpatient hospitalization for initiation of treatment, such as when acute illness (e.g., pneumonia or soft tissue infection), advanced comorbid disease (e.g., heart failure or liver failure) or uncontrolled psychiatric illness (e.g., bipolar affective disorder) makes ambulatory or IOP treatment unfeasible.

114. Additionally, there is a subset of individuals who require intensive care due to their co-occurring mental health conditions and other factors, such as recurring incarceration and/or homelessness, which complicate their treatment. For these individuals, the Assertive Community Treatment (ACT) model has been shown to be effective in improving their treatment outcomes and ultimately cost-effective to the community overall.^{358, 359, 360, 361, 362, 363} Through this model, an interdisciplinary team with a psychiatrist, two psychiatric nurses, two employment specialists,⁹ two SUD specialists, a peer recovery coach, an administrative program staff, and social workers or other masters or doctoral level professionals, work with clients to provide comprehensive and intensive services.³⁶⁴ These services include assistance with activities of daily living, substance use and mental health treatment, employment support services and developing other recovery skills, administration and monitoring prescriptions, and provision of interventions with support networks as needed.
115. In Lake County, Lake-Geauga Recovery Centers offer residential treatment programs.³⁶⁵ In 2019, 171 county residents were served by the residential treatment supportive housing programs.³⁶⁶ During this time, 52% of women and 57% of men completed residential treatment, meeting all treatment milestones. This rate of completion is higher than the national average of 40% to 44%.³⁶⁷ Additionally, the majority of individuals who completed residential treatment, maintained sobriety a year after completing residential treatment.³⁶⁸ In Trumbull County, Compass Family and Community Services provides ACT and other residential treatment services.³⁶⁹ Meridian HealthCare also provides comprehensive OUD treatment including withdrawal management, residential treatment, and supportive housing.^{370, 371}
116. Components of abatement interventions. In conjunction with support to efficiently connect individuals to treatment as described in Section 2A, treatment capacity and infrastructure in Lake and Trumbull Counties should be expanded to meet the needs within the Communities. Individuals with OUD in the Communities should have timely access to appropriate treatment based on their need, whether ambulatory, IOP, residential, or inpatient care. It is crucial that individuals with OUD receive high-quality care to maximize retention and outcomes. Additional efforts should also focus on reaching and providing treatment to vulnerable populations such as adolescents, individuals both within and newly released from the criminal justice system, and individuals who are homeless. Since such individuals are less likely to utilize ambulatory practice for preventive or chronic care needs, interventions such as mobile health care teams can serve an important role in increasing access to and continuity of care. The Communities should also continue to scale telehealth services for MAT induction and continuation,³⁷² in part given the rurality of Trumbull County. ACT teams should also be supported within the Communities to improve treatment outcomes for hard-to-treat individuals.
117. In conclusion, abatement programs within the Communities should include further investments in the treatment system so as to allow for the provision of additional comprehensive, coordinated high-quality care for individuals with OUD, including access to services for the identification and management of acute, chronic and preventive care needs.³⁷³ Only a minority of residents who could benefit from treatment are receiving it, and more must be done to connect individuals to appropriate services. Such investments should also be targeted at each specific point where gaps occur or individuals otherwise experience unacceptably high rates of relapse or loss to follow-up, ranging from the identification and triage of

⁹ I do not include employment specialists in my Redress Models as I consider these services to be subsumed in Section 3C.

patients after non-fatal overdose to the expansion of induction and IOP programs to the provision of compassionate, evidence-based care for individuals living in recovery.

C. Managing Complications Attributable to the Epidemic

The goal of this abatement remedy is to provide unfettered access to high quality, longitudinal, compassionate and comprehensive treatment to individuals in the Communities with OUD who have complications from the disorder. Such complications include chronic infectious diseases, such as hepatitis C (HCV) or HIV, acquired through the sharing of needles during injection drug use, as well as endocarditis and valvular heart disease, complications from blood-borne bacterial infections that can seed the heart valves and cause significant morbidity and mortality.

118. An estimated 4.1 million people in the U.S. are infected with HCV³⁷⁴ and 1.1 million are infected with HIV, with about 25% of HIV cases co-infected with HCV.^{375, 376} Individuals that are co-infected with HIV and HCV have a greater risk for chronic liver disease and liver-related death than individuals living with HIV alone. While studies suggest only a small proportion of individuals with non-medical opioid use progress to heroin,³⁷⁷ there are nevertheless millions of individuals who report such non-medical opioid use in the United States. Injection drug use (IDU) is a primary risk factor for the acquisition and transmission of both HCV and HIV, and the opioid epidemic has resulted in a sharp increase in both of these diseases. From 2012 to 2016, the CDC estimated acute HCV infections increased by approximately 70%,³⁷⁸ and states with the highest rate of new HCV infections, such as West Virginia, Kentucky, and Tennessee, were also among those that have been hardest hit by the opioid epidemic.³⁷⁹ Several studies have reported significant associations between the opioid epidemic and HCV.^{380, 381}
119. In 2019, 148 Ohioans were diagnosed with HIV associated with injection drug use, representing 15% of all new HIV diagnoses.³⁸² In the same year, only 7% of new HIV diagnoses in the United States were among PWID. Within the subregion of Ohio that contains Trumbull County, fewer than half (43%) of people living with HIV were linked to care within 30 days of diagnosis in 2019; in Ohio overall, nearly three in four (74%) people newly diagnosed with HIV were linked to care within 30 days.³⁸³ In 2019, 10.8% of people living with diagnosed HIV in Lake County acquired HIV due to injection drug use.³⁸⁴
120. One example of a microcosm illustrating the interconnectedness of the opioid epidemic and HIV and HCV infections was seen in rural Scott County, Indiana. In 2015, this rural county experienced a community outbreak of HIV, and by April 2016, there were 188 confirmed cases of HIV infection, of which 92% were coinfecting with HCV.³⁸⁵ The Indiana State Department of Health led an investigation into this outbreak and determined it to be linked to the injection of the prescription opioid oxycodone.³⁸⁶ This outbreak also highlighted the vulnerabilities of communities to handle these crises.^r Based on the criteria established by the CDC, Lake and Trumbull Counties are considered at-risk of an HIV outbreak and are already experiencing an HCV outbreak associated with injection drug use.³⁸⁷
121. Individuals in the Communities with OUD should be targeted for HCV and HIV screening and referral, since the effectiveness and cost-effectiveness³⁸⁸ of screening for HCV and HIV is well-established. There are many opportunities for screening individuals with OUD, including at EDs, residential or outpatient treatment facilities, syringe services programs, and jails and prisons. In particular, efforts should be focused on screening individuals who inject drugs and share injection equipment. The CDC recommends such individuals be tested for HIV annually;³⁸⁹ HCV screening should also be performed annually and jointly with HIV screening,³⁹⁰ allowing for the effective use of existing infrastructure and resources to address both diseases. Additionally, integrating HCV and HIV testing and counseling programs may reinforce prevention education messages to reduce risky behavior among high-risk populations such as PWID.³⁹¹

^r Of note, NIDA cites the implementation of a syringe services program as a major factor helping to bring this HIV outbreak under control. (Available at: <https://www.drugabuse.gov/about-nida/noras-blog/2016/12/syringe-exchange-programs-are-part-effective-hiv-prevention>)

122. It is crucial that HCV and HIV screening is effectively linked to post-test services and support including treatment and counseling, since the performance of screening without proper and effective referral channels could lead individuals to miss out on timely initiation of prophylaxis and treatment, which may accelerate disease progression and lead to an increased transmission rate within the community. The safety and effectiveness of HCV treatment has improved markedly during the past few years with several new FDA-approved medications. Current HCV treatments usually require just 8 to 12 weeks of oral therapy and can cure over 90% of patients with few side effects.³⁹² Early HCV treatment helps to prevent or limit the development of cirrhosis, lowering the risk of developing liver cancer, liver failure, and other complications in addition to limiting the risk of HCV transmission to sexual partners or children, increasing survival, and improving quality of life.³⁹³ As a result, HCV treatment is cost-effective.^{394,395} However, patients can be re-infected with HCV, reinforcing the need for SSPs to be easily accessible to prevent the spread of HCV.
123. Timely HIV treatment is also important as it significantly improves survival and quality of life, limits HIV transmission, and slows the progression of the disease.³⁹⁶ HIV is a chronic condition that currently requires lifelong treatment and monitoring, and as a result, continued treatment services are critical as lapses in care could lead to suboptimal outcomes and continued HIV transmission.³⁹⁷
124. Endocarditis is another rare but serious complication of OUD and has long been regarded as one of the major causes of morbidity and mortality among those who inject drugs.³⁹⁸ Infective endocarditis (IE), or infection and inflammation of the heart valves and lining of the heart chambers, is caused by bacteria entering the blood stream and attacking heart valves. Acute endocarditis is especially severe and common among PWID and often results in additional infection, or septic emboli, of the kidneys, lungs, and brain.³⁹⁹ In one recent report, hospitalizations for endocarditis increased twelve-times among individuals with drug dependence in North Carolina between 2010 to 2015; one-third of individuals were infected with HCV and the average cost of each hospitalization exceeded \$50,000.⁴⁰⁰ In another report using the Health Care and Utilization Project National Inpatient Sample (HCUP-NIS), the proportion of IE-related hospitalizations that were attributable to IVDU increased from 7.0 to 12.1% between 2000 and 2013, which the authors noted “appear to mirror those of the intertwined prescription opioid, heroin, HCV, and overdose epidemics throughout the country.”⁴⁰¹ These findings are important because of the morbidity associated with the disease, with estimates of in-hospital mortality as high as 11 to 26% and 5-year mortality as high as 12 to 50%.^{402,403,404} Compared to IE patients that did not inject drugs, PWID with IE have a significantly higher likelihood of open cardiac surgery, longer hospital stays and nearly 1.5-times higher hospital costs.⁴⁰⁵ Additionally, a study from Boston, Massachusetts found that despite PWID being younger and having fewer cardiovascular risk factors than non-PWID with IE, PWID patients had nearly a four-times higher risk of valve-related complications.⁴⁰⁶ Among individuals with IE involving the right side of the heart, injection drug use was noted among approximately one-third (29.5%) of individuals in a literature review of 262 individuals from 2008 to 2013.⁴⁰⁷
125. One nationwide study found the overall incidence rate of IE associated with IVDU increased over 250% between 2009 (30 per 10,000 cases) and 2016 (79 per 10,000 cases).⁴⁰⁸ Another study at The Ohio State University Wexner Medical Center, found a 436% increase in IE cases associated with IVDU, from 33 to 177 between 2012 and 2017.^{409,410} The majority of these cases were due to heroin IVDU. Nearly half (49%) of the patients were re-hospitalized and 40% relapsed; between 2012 and 2017, the death rate increased from 9% to 25%.⁴¹¹
126. Endocarditis treatment initially requires inpatient hospitalization and intravenous antibiotic administration. In some cases, the damage to the heart valve is so severe that it must be replaced surgically. Unfortunately, complications such as lack of response to antibiotics or embolization that causes strokes

may occur, and also prove fatal. These cases pose a high burden on hospitals in the Communities because of their social and clinical complexity and because of the very high risk of rehospitalization if IVDU is not discontinued. However, hospitalization represents an opportunity for delivery of addiction counseling, enrollment in treatment, and education on harm reduction strategies.

127. Many barriers will have to be overcome to consistently provide high quality, longitudinal, compassionate and comprehensive treatment to individuals with complications from OUD such as those described above. For example, one study surveyed 333 patients living with HIV between 2007 and 2008 to examine barriers to support service use and factors associated with need and unmet need for services.⁴¹² The analysis found that 71% of patients reported needing at least one supportive service. Barriers to accessing such services included lack of information (47% reported not knowing where to go or who to call); administrative burdens (33% reported the system too confusing and/or the wait list too long); and financial or logistical barriers (18% reported treatment too expensive and/or transportation problems). A survey of individuals with HCV, including some also with HIV, between November 2013 and July 2015, found that over 93% of participants wanted HCV treatment but approximately half were unable to spend anything out of pocket for their treatment.⁴¹³ In addition to cost, participants also reported that access to medications and provider reluctance delayed treatment initiation.
128. Components of abatement interventions. Proactive surveillance, screening efforts, and treatment for complications attributable to the opioid epidemic should be supported in Lake and Trumbull Counties. Based on the scientific evidence for HIV and HCV prevention and treatment, all individuals with OUD, especially those who inject drugs, should be screened annually for HIV and HCV. Additionally, individuals who test positive for HIV or HCV, or have acquired HIV or HCV because of the opioid epidemic, should receive comprehensive health care for their disease. This not only includes medications for HIV or HCV, but also care for other associated acute, chronic and preventive needs. In addition to intravenous antibiotics and other direct clinical care, those with infectious endocarditis attributable to the opioid epidemic should also be linked with OUD treatment and recovery services upon hospital discharge.
129. In conclusion, the opioid epidemic has had many ripple effects, and transmission of HIV and HCV among people who use drugs has flourished in settings such as Lake County and Trumbull County due to increases in the number of individuals with OUD. Fortunately, HIV and HCV are well understood diseases, and effective treatments, and in the case of HCV, curable ones, exist. Many barriers must be overcome to achieve the widespread screening and treatment that is required to abate these elements of the opioid epidemic within the Communities, and individuals with other costly and complex sequela of the epidemic, such as infectious endocarditis, also require special clinical care, coordination and support. As with other programs proposed in my abatement plan, these components have a favorable return on investment and will help individuals avoid preventable adverse events related to these infectious diseases.

D. Workforce Expansion and Resiliency

The goal of this remedy is to expand the healthcare workforce, since the Communities benefits from well-trained healthcare professionals who are equipped to deliver services for those living with chronic pain and/or OUD. The workforce must be trained and equipped to meet the needs of residents in the Communities, and to provide evidence-informed services to address the social and medical harms associated with the opioid epidemic.

130. Workforce training and expansion. A well-trained healthcare workforce is central to any program to address prevention and treatment of OUD and other morbidity and mortality arising from the opioid epidemic. Also, workforce expansion is a necessary, readily-overlooked component of any effort to build treatment infrastructure.⁴¹⁴ A well-trained workforce can follow evidence-informed guidelines for pain treatment, can help to provide medication for OUD treatment,⁴¹⁵ and can address a variety of health needs arising from the opioid epidemic. Complementary mechanisms can help to prepare the workforce, including greater training through existing graduate health professional education programs (Section 1A), as well as capacity-building through expansion of existing infrastructure and the creation of new programs for health care professionals and paraprofessionals.⁴¹⁶
131. Workforce assessment. Given the scope of the challenge, the Communities should consider a systematic workforce assessment to determine gaps in the available supply and core competencies of the clinical and social service workforce available to address the opioid epidemic. Such an assessment would explore the available supply of managerial and administrative professionals, nurse and medical practice leaders, social workers and case managers, recovery coaches and paraprofessionals available to assist people with OUD. The assessment would explore the workforce's core technical and cultural competencies regarding pertinent OUD treatment and service interventions.
132. MAT providers. Across the U.S., many providers do not prescribe buprenorphine to their maximum patient limit. Additionally, providers may not be evenly dispersed and accessible across Lake and Trumbull Counties. Measures to address known organizational barriers and to improve provider confidence and expertise in addressing addiction may be helpful in addressing these challenges. For example, some communities have found success in establishing comprehensive clinics where community providers can dedicate time to seeing patients for addiction treatment that is distinct and separate from their regular practice.⁴¹⁷ Although such an effort continues to segregate addiction care, in some settings it has increased provider capacity and given support to health care professionals. Greater deployment of nurse practitioners with primary care expertise may also help to expand patient access to MAT.⁴¹⁸
133. Pain specialists. Any workforce assessment can also help to evaluate the level of community need for additional pain specialists. Such individuals may include both physicians and non-physicians who are well trained, highly experienced and knowledgeable about integrative care that combines pharmacologic and non-pharmacologic treatments for pain. This is particularly important within the Communities, where the average age of the population is older than the rest of Ohio.^{419,420} Additionally, a study of 356 individuals with OUD in Dayton, OH, found that over half (55.9%) report chronic pain,⁴²¹ highlighting the need to treat chronic pain with alternatives for prescription opioids for individuals with OUD. Furthermore, the Lake County Community Health Improvement Plan noted that men in the labor, maintenance, and trade occupations are at a higher risk of drug overdose death.⁴²² Given the increased risk of injury and chronic pain associated with these occupations and high prevalence of chronic pain among older populations, it is clear that there is a need for additional specialists to treat pain and reduce the reliance on prescription opioids.

134. Compassion Fatigue and Workforce Resiliency. Compassion fatigue has been referred to as the “cost of caring” with symptoms that mirror post-traumatic stress disorder.⁴²³ Repeated exposure to traumatic experiences, such as multiple overdoses and overdose-related deaths among young people, impact emergency responders emotionally, behaviorally, interpersonally and physically. Compassion fatigue and burnout result in increased turnover and decreased empathy. A survey of behavioral health and emergency preparedness responders found that nearly three in four (72%) were at risk of compassion fatigue and nearly one in five (19%) were at risk of burnout.⁴²⁴ Importantly, fewer than one in four (22%) had high resilience, which is associated with decreased likelihood of compassion fatigue and burnout. Programs to build resilience, self-efficacy and a supportive social network among first responders are crucial to promoting a safe and healthy community. The City of Huntington’s Compass project serves as one such program; it focuses on developing tools and a foundation to cope with high-stress situations, such as self-care skills, wellness resources, and nutrition and exercise.⁴²⁵ A literature review of 25 studies assessing interventions to reduce burnout found that a combination of person-level (e.g., mindfulness, self-care, coping) and organization-directed interventions (e.g., professional support systems or “buddy systems,” workplace policies) found positive effects and reduced burnout lasted for at least one year, whereas the positive effects of person-level interventions alone lasted for only six-months.⁴²⁶
135. Components of abatement interventions. As noted in the local Community Health Improvement Plans, there is a need to expand the healthcare workforce within Lake and Trumbull Counties. There are four major components to an expanded health care professional and paraprofessional workforce: (1) conducting a workforce assessment to determine key staff and training needs in the Communities; (2) expanding the number of MAT providers; (3) expanding the number of medical social workers (4) creating and expanding programs that address burnout/compassion fatigue. Medical social workers should be expanded and incorporated into EDs within the Communities, where they can assist in linking individuals to treatment and community resources. In order to maintain the workforce resiliency within the Communities, compassion fatigue programs should be made available for first responders and professionals whose clients have OUD or are affected by the opioid epidemic such as nurse practitioners.
136. In conclusion, an effective response to the opioid epidemic must include investments in the Communities’ healthcare workforce to address prevention as well as evidence-based pain and OUD treatment. The workforce must include medical social workers in order to provide wrap-around services and address the psychosocial needs of individuals with OUD and their families. Finally, programs should be supported and deployed to ensure the resiliency of the current and future workforce.

E. Distributing Naloxone and Providing Training

The goal of this remedy is to expand upon and support the efforts of the naloxone distribution and training that is currently being done in the Communities. This is important because naloxone is an opioid antagonist, or "blocker," that can save lives by safely and rapidly reversing opioid overdoses. However, its costs, stigma, and other barriers have historically limited accessibility to those in need.

137. Naloxone works by binding to opioid receptors and blocking respiratory depression and other effects of prescription opioids and heroin, or illicit fentanyl, if someone has opioids in their system. It comes in three FDA-approved formulations: injectable, autoinjector delivered, and nasal spray ("Narcan"). Though injectable naloxone is the least expensive, use of the injectable formulation requires professional training.
138. Naloxone is a non-scheduled prescription medicine rather than a controlled substance, and there is widespread consensus that naloxone distribution and training represent an important method to reduce opioid-related overdose.⁴²⁷ In a randomized controlled trial, intranasal naloxone reversed heroin overdose successfully in 82% of patients,⁴²⁸ and naloxone distribution and training programs have also shown over 80% effectiveness at reversing overdoses in community settings.^{429,430} In a systematic review of take-home naloxone programs for individuals likely to witness an opioid overdose, naloxone was associated with successful overdose reversals in 96.3% of the patients (2,249 successful overdose reversals among 2,336 administrations).⁴³¹ It is important to note that there is no evidence to support that naloxone use encourages and enables drug use.^{432,433}
139. Many other community-level evaluations have been performed. For example, a study of 19 geographically distinct cities and towns in Massachusetts found that opioid overdose death rates were 27% to 46% lower in communities where overdose education and naloxone distribution had been implemented.⁴³⁴ A study of a naloxone distribution program in North Carolina suggested that counties in the state that distributed naloxone kits had a 10% to 12% lower opioid overdose death rates compared to their counterparts, avoiding 352 overdose deaths between 2013 to 2016. A recent study found that states that allow direct dispensing of naloxone by pharmacists (or, "direct authority") were associated with a significantly reduced rate of fatal opioid-overdoses.⁴³⁵ Public lock boxes, similar to boxes with automated external defibrillators (AEDs), containing naloxone have been implemented in Rhode Island and Ohio, and are one method to ensure community access of naloxone where overdoses may frequently occur (e.g., libraries).⁴³⁶
140. Within the Communities, naloxone distribution and training are provided through Project DAWN (Deaths Avoided With Naloxone).⁴³⁷ Through this program, participants receive a take-home naloxone kit and training on: recognizing the signs and symptoms of an overdose; distinguishing different types of overdoses; performing rescue breathing; contacting emergency medical services; and administering intranasal naloxone. From my discussion with Lauren Thorp, I learned that this program received publicity when it was first implemented in the Communities. Additional outreach and media coverage must continue to ensure its use and attendance by community members. Between 2017 and 2018, Trumbull County distributed over 800 take-home naloxone kits to community members through Project DAWN.⁴³⁸
141. Despite its benefits, naloxone distribution and training will have a finite impact on the opioid epidemic. Not all overdoses are witnessed by someone willing and able to administer naloxone. In addition, the long-term public health impact of naloxone programs depends on what happens after an overdose is successfully reversed.⁴³⁹ For example, successfully revived individuals remain vulnerable to future overdose and death, and individuals who overdose once have escalating risks of future overdoses. After naloxone, individuals may temporarily or permanently abstain from use, continue as active users, obtain addiction treatment, overdose again, or die of other causes. Naloxone distribution must be accompanied by direct training, and its role in reversing overdoses should also be considered for inclusion in educational

campaigns. Ultimately, the outcomes of an overdose reversal depend upon the availability and comprehensiveness of OUD treatment, other mortality risks, and background factors. These factors underscore the importance of a comprehensive abatement approach.

142. Components of abatement interventions. Efforts to support naloxone distribution, training, and use can be categorized in four distinct channels in Lake and Trumbull Counties.^s First, first responders, such as law enforcement officers, firefighters, and paramedics and emergency medical technicians (EMTs), should be provided with naloxone and training, since these individuals often serve as the initial point of contact with those who have overdosed. Second, EDs within the Communities should have sufficient naloxone doses for hospitalized overdose cases and doses to expand access to take-home naloxone once patients are discharged. Third, high-risk patients, such as those who are maintained on chronic, high-dose prescription opioids or who have already experienced a non-fatal overdose, should be prescribed naloxone and trained on how to administer it. Such individuals can be reached through ambulatory and community-based programs, or as is already done by the QRTs in Lake County and Newton Falls, on follow up visits after an overdose. In many cases, such training should also include their social network, caregivers, and/or family members, given the likelihood that these individuals would be most likely to respond to an overdose. Another group of high-risk individuals who should receive naloxone are individuals who have OUD and were recently incarcerated and upon release from incarceration. For example, a study in North Carolina examined the difference in opioid overdose death rates between former inmates and general residents found that former inmates were 40 times more likely to die of an opioid overdose than someone in the general population.⁴⁴⁰ Finally, naloxone should be distributed throughout the Communities in public lock boxes, similar to automatic external defibrillators which are routinely available in movie theaters, malls, schools, airports, and houses of worship. This will improve the capacity of bystander rescuers to save the lives of opioid overdose victims.
143. In conclusion, abatement programs within the Communities should ensure that naloxone is readily available to all in need, including first responders and high-risk patients, as well as distributed effectively in public spaces. Naloxone distribution should be accompanied by direct training, and its role in reversing overdoses should also be considered for inclusion in educational campaigns as discussed elsewhere herein. Community outreach and media campaigns should be continuously run to increase awareness and knowledge of naloxone availability and training.

^s Additional formulations and continued innovation in the naloxone market are likely, and abatement remedies should remain flexible to keep pace. For example, a new naloxone formulation may be developed that has a significant comparative advantage over currently available formulations.

CATEGORY 3: RECOVERY – ENHANCING PUBLIC SAFETY AND REINTEGRATION

A. Public Safety

Law enforcement officers are in a key position to help reverse the opioid epidemic in the Communities as they respond to overdoses and engage in public health oriented policing interventions. Despite this, police departments, as with other local agencies, have been stretched thin because of the demands of the opioid epidemic, diminishing their ability to address other public safety needs. The abatement interventions proposed in this report, combined with the expansion of social workers and mental health personnel in the Communities, will address or prevent many of the calls that police and other first responders currently have to respond to. However, in addition to expansion of treatment and mental health services, there is also a need for a greater number of specialized detectives who can focus on the opioid epidemic, as well as stigma reduction training and pretrial diversion, that can equip the broader police force responding to it.

144. Training to reduce stigma. Since law enforcement officers are often the first responders to an overdose, it is important to support law enforcement within Lake and Trumbull Counties to have the training and confidence to appropriately respond.^t Similar Crisis Intervention Team (CIT) training has been conducted extensively throughout the Communities, including 11 Police Departments throughout Trumbull County, the Trumbull County Sheriff's Department, and the City of Mentor Police Department in Lake County.^{441,442} While not focused on opioid overdose per se, CIT training for officers to reduce stigma related to behavioral health crises has been effective at improving officers' attitudes toward individuals with mental health issues^{443,444} and self-efficacy in handling these calls.^{445,446} Such training has also reduced arrests and use of force,⁴⁴⁷ and increased referrals for services during a mental or behavioral health crisis.^{448,449} Such training, which should be repeated at regular intervals, may reduce stigma by law enforcement towards people with OUD, increase the likelihood that individuals will call 911 for help, and improve referrals for services and/or treatment.
145. Pretrial Diversion. Pretrial diversion, sometimes referred to as Law Enforcement Assisted Diversion (LEAD), offers eligible individuals who would otherwise be arrested for drug-related charges the opportunity to instead access community-based services and/or treatment.⁴⁵⁰ These programs are unique in that they occur pre-booking so that if an individual who qualifies for the program chooses to enroll, they do not have an arrest on their record if they complete program requirements. Qualifications are typically based on having committed a low-level drug offense and factors such as the amount of drugs possessed, absence of any intent to distribute, absence of disqualifying criminal history such as violent crime, and are determined by a social worker/mental health professional that is embedded in the police department.⁴⁵¹ Thus, in contrast to drug courts, LEAD participants never enter the criminal justice system and they are enrolled in the program instead of being charged with a crime. Diversion programs reflect partnerships between law enforcement and local behavioral health systems to enroll individuals in appropriate services.^u LEAD pretrial jail diversion programs are designed to expedite treatment for individuals with substance use disorders while reducing strain on the criminal justice system.
146. Seattle created the first LEAD program and early evaluation results suggest improved outcomes for participants including housing, employment, and reduced recidivism.^{452, 453} For example, LEAD participants with suspected low-level drug offenses had fewer arrests and felony charges, shorter jail time, and less interaction with the legal and judicial system.^{454,455} Additionally, participants were twice as likely to have been sheltered, 90% more likely to have permanent housing, and almost half were either employed

^t Law enforcement officers within prisons and detention centers should also undergo similar training, given high rates of stigma in these settings as well.

^u Such programs extend and formalize informal diversion that may take place when, for example, law enforcement bring an individual who overdosed to an Emergency Department rather than detention facility for evaluation, treatment and referral to treatment.

or in vocational training.⁴⁵⁶ Despite differences in state laws and client intake processes, there are examples of successfully implemented LEAD programs, modeled after Seattle's experience.⁴⁵⁷ For example, a West Virginia LEAD program reports that half of the individuals contacted by the LEAD program have entered some form of treatment.⁴⁵⁸ Since approximately half of inmates will re-enter custody despite currently available rehabilitation opportunities,⁴⁵⁹ LEAD programs are one important means of reducing the rate of individuals with low-level drug offenses from being incarcerated and addressing environmental factors that contribute to repeat offenses among individuals with OUD. As with CIT training, law enforcement officers require training that should be repeated at regular intervals to maximize their familiarity and expertise with the conduct of LEAD. As of December 2019, West Virginia LEAD programs have diverted more than 250 people from the criminal justice system; 66% percent of program participants have not been re-arrested.⁴⁶⁰

147. Specialized opioid units. Some police departments have created specialized units to address the opioid epidemic. These units, such as one in Cleveland, Ohio,⁴⁶¹ are often comprised of detectives, sometimes within homicide or narcotics units, who work to link together overdose incidents across the city by identifying similar contacts, sources, dealers or other features between overdose events. These units treat sites of overdoses as crime scenes and work to track back to dealers and build cases for prosecution to bring down higher level supply sources for opioids.⁴⁶² The optimal specific size and composition of these units, as with other components of an effective law enforcement response to the epidemic, will depend upon many features of the local community, including the size and urbanicity of the jurisdiction as well as the burden of prescription opioids, heroin, and illicit fentanyl.
148. Components of abatement interventions. LEAD programs should formally be established in police departments in the Lake and Trumbull Counties in order to divert as many qualified individuals as possible. The optimal size of any LEAD program depends upon the size of the population served by a police department and the burden of the epidemic within the community. Additionally, police departments should create specialized overdose units to investigate and disrupt higher-level opioid trafficking. As with LEAD programs, the size of specialized opioid units will depend on local factors such as levels of drug trafficking and the size of population served by the police departments. It is important that police and correctional officers receive continuous stigma reduction training, so they are better prepared when interacting with individuals with OUD or who have overdosed.
149. In conclusion, law enforcement plays a vital role in an effective public safety response to the opioid epidemic, and abatement programs in the Communities should include resources to support a variety of different functions. While the specific needs of local law enforcement could extend beyond the areas identified above, at a minimum, resources should be committed to ensure adequate support training to reduce stigma, pretrial diversion, and one or more specialized overdose units.

B. Criminal Justice System

The criminal justice system is a major thoroughfare for individuals with opioid addiction and represents an opportunity to identify and link those individuals to treatment, reducing their risk of overdose and recidivism while improving their societal reintegration. This remedy also focuses on ways that the criminal justice system can positively impact the opioid epidemic in the Communities, such as by building upon the Drug Courts and reentry programs in Lake and Trumbull Counties.

150. The opioid epidemic has burdened the U.S. criminal justice system with a surge of inmates, increasing health care costs associated with OUD and producing high rates of overdose and recidivism. Data from the Department of Justice suggest over half of the incarcerated population nationwide has a substance use disorder,⁴⁶³ approximately one in four state prisoners nationwide between 2007-2009 reported prior heroin or opioid use,⁴⁶⁴ and by some estimates, as many as one-fourth to one-third of individuals with heroin addiction are estimated to pass through the criminal justice system each year.⁴⁶⁵ Similarly, a study of individuals with OUD in Akron, Ohio, found that nearly one-third (30.9%) of respondents had been incarcerated within the previous six months.⁴⁶⁶ A 2015 intake study by the Ohio Department of Rehabilitation and Correction reports that four in five (80.3%) inmates reported recent substance use or treatment for substance use.⁴⁶⁷
151. Treatment for OUD. Nationally, fewer than 20% of individuals with substance use disorders in the criminal justice system receive treatment,⁴⁶⁸ and what treatment is received is often inadequate. According to the Federal Bureau of Justice Assistance, as of August 2017, only 30 of the 5,100 (0.6%) prisons and jails in the U.S. offered opioid users methadone or buprenorphine,⁴⁶⁹ despite evidence that such treatment improves treatment entry and retention after release if arrangements exist to continue treatment.⁴⁷⁰ Because of this, induction facilities and access to MAT, as well as other treatments along the continuum of care, are important for those incarcerated in jails, prisons or juvenile detention facilities. While MAT should be made available to anyone with OUD, such treatments are especially important for high priority populations such as pregnant women with OUD and individuals already on MAT prior to incarceration.⁴⁷¹ Within the Lake County Adult Detention Center, the Jail Treatment Program is offered by Crossroads Health and is an intensive outpatient level of care.⁴⁷² In 2018, more than 350 individuals received treatment for OUD through the Jail Treatment Program.⁴⁷³
152. Drug courts. There is substantial evidence regarding the role that drug courts can play in diverting non-violent offenders from the criminal justice system to the treatment system, where their needs can be more effectively addressed.⁴⁷⁴ These programs represent special court dockets that provide judicially-supervised substance use treatment in lieu of incarcerating individuals with drug-related offenses. The President's Commission on Combatting Drug Addiction and the Opioid Crisis included a recommendation that the "DOJ [Department of Justice] broadly establish federal drug courts within the federal district court system in all 93 federal judicial districts." Further, the Commission reported "States, local units of government, and Indian tribal governments should apply for drug court grants established by 34 U.S.C. § 10611. Individuals with a SUD who violate probation terms with substance use should be diverted into drug court, rather than prison."⁴⁷⁵
153. One of several sources of evidence to support the efficacy of drug courts is a comprehensive review commissioned by the U.S. Department of Justice that examined drug courts in the U.S.; the report, which was also supported by the Office of National Drug Control Policy (ONDCP) of the Executive Office of the President, found that the combination of comprehensive treatment services and individualized care provided by drug courts is an effective way to provide treatment to criminal offenders with substance use disorders.⁴⁷⁶ A study conducted by the U.S. Department of Justice found that drug court participants reported less drug use, lower rates of positive drug tests, and fewer rearrests than comparable offenders

who did not participate in drug courts.⁴⁷⁷ Though treatment investment costs are higher for individuals participating in drug courts, the reduced recidivism resulted in an average savings of \$5,680 to \$6,208 per offender. Additionally, a meta-analysis of 154 studies found that adult drug courts reduced drug-related recidivism from 50% to 37%.⁴⁷⁸

154. Reentry programs. Individuals released from prisons and jails face a multitude of issues that make their reintegration into the community challenging, including substance use or mental health problems and having no or little qualifications and skills that make them employable.^{479,480} To address this issue, many jurisdictions in the U.S. have developed and implemented reentry programs that include substance use treatment, mental health services, transitional housing, education and job readiness assistance, and employment services.^{481,482} A study of young offenders aged 16 to 25 years enrolled in the Substance Use Treatment and Reentry (STAR) Program in Los Angeles found over 70% were still employed a year after initiating the program, self-reported arrests were below 15%, and there was a reduction in substance abuse among participants that reported drug use at intake.⁴⁸³ A study of Florida inmates between January 2006 and December 2008, found that reentry and transitional substance use programs had some of the largest effects on increasing employment and reducing recidivism.⁴⁸⁴ In 2018, the Council of State Governments Justice Center, sponsored by the U.S. Department of Justice, released guidelines for “Best Practices for Successful Reentry for People Who Have Opioid Addictions” that describe efforts local agencies can implement to ensure successful reentry.⁴⁸⁵ Successful reentry programs must simultaneously assess the need for, and deliver to participants, supportive services and programs across a number of dimensions, including housing, education, employment, health and well-being, and family reunification and support.⁴⁸⁶
155. Components of abatement interventions. Abatement efforts should focus on expanding the capacity of the Lake County and Trumbull County Drug Courts so that enough spaces are available to divert and treat as many qualified individuals with OUD as possible. Juvenile drug courts should also be expanded in the Communities to prevent the negative effects of early incarceration. For these efforts to be successful, the Courts must be equipped with a sufficient number of court dockets, support staff and wrap-around services including social workers and case managers. Additionally, all individuals (re)entering the criminal justice system should be screened for OUD and individuals who need treatment must receive appropriate care, including MAT, while incarcerated. Inmates released while still receiving treatment should be closely linked to agencies and organizations that provide treatment upon reentry to avoid lapses in treatment and suboptimal treatment outcomes. Moreover, individuals with OUD released from jails or prisons should be linked to existing reentry programs that provide transitional housing for those who are at a high risk of homelessness, social services, and jobs/vocational training. Efforts in the Communities should focus on expanding capacity to accommodate those in need of reentry programs and should invest in creating and expanding programs to provide comprehensive social services.
156. In conclusion, a large proportion of individuals with OUD, or who have otherwise been impacted by the opioid epidemic, come into contact with the criminal justice system each year, including within the Communities. Because of this, as well as the demonstrated benefit of interventions such as MAT, drug courts, reentry programs and jobs training for those with OUD, many further investments are needed. Such investments will not only be of direct benefit to the participating individuals, but also of broader societal benefit as they strengthen families, enhance community reintegration and help local areas hard hit by the epidemic to recover.

C. Vocational Training, Education, and Job Placement

The goal of this remedy is to promote economic development to make gainful employment readily available to individuals in the Communities with OUD or who have been otherwise impacted by the opioid epidemic. This is important because of the complex but beneficial relationship between employment and recovery.⁴⁸⁷

157. Jobs training and placement services for individuals with OUD. The opioid epidemic has been particularly profound in many parts of America that have simultaneously experienced significant economic decline, including Ohio communities such as Lake County and Trumbull County. While the relationship between economic hardship and opioid morbidity and mortality is complex,^{488,489} there is widespread consensus that jobs training is important for under- and unemployed individuals with OUD.⁴⁹⁰ Unemployment is a significant risk factor for substance use and relapse, and OUD is itself a significant employment barrier, yet not⁴⁹¹ a qualifying condition for federal disability programs.^{492,493} Many people living with OUD face other employment barriers, including educational challenges⁴⁹⁴ and co-occurring physical or mental health challenges, that may be addressed in vocational services, including those offered within addiction treatment.⁴⁹⁵ For these reasons, comprehensive treatment programs, as well as diversion and reentry programs, often include vocational training and job placement. It is important that vocational training programs incorporate pre-employment preparation, gradually increasing hours and work responsibility, and ongoing support from counselors and peers.⁴⁹⁶ Existing data suggest that vocational services within substance use disorder treatment are cost-effective,⁴⁹⁷ though such programs face many barriers in creating successful paths to employment. Trials are now underway to explore the effectiveness of alternative models.⁴⁹⁸
158. Expanded job opportunities to meet local needs created or worsened by the opioid epidemic. There is also widespread consensus that the opioid epidemic itself has created new challenges with implications for the healthcare workforce within affected communities. These challenges may be met through proper training and deployment of health care professionals and paraprofessionals. Workforce needs span the spectrum from community health workers to case managers to child protection staff, social workers, nurses, and other professionals able to serve individuals and families directly affected by OUD. Some of these roles, such as peer navigators, can be effectively performed by individuals with lived experience of OUD.^{499,500} Other roles can be filled by other residents in the Communities.
159. Recovery-supportive workplaces. Incorporating peer support and case management services, or mentor support within workplaces, have been linked to successful workplace reintegration.⁵⁰¹ Employers can foster workplace environments that welcome individuals in recovery, and that seek to reduce addiction stigma.⁵⁰² Employers can anticipate and address predictable challenges employees may face. For example, they can make available onsite or telehealth counseling for both scheduled and on-demand recovery support. To reduce both absenteeism and missed appointments, employers can facilitate peer support groups designed around workers' daily schedules. Work sites can openly support MAT, and ensure that health plans comply with the letter and spirit of mental health and addiction parity requirements which are intended to ensure proper access to Suboxone and other therapies.⁵⁰³ Other measures, such as incorporating vocational rehabilitation counselors (i.e., peer recover coaches or case managers) can help ensure support for both workers and employers.⁵⁰⁴
160. Accountability and safety measures. To be effective and sustainable, public workplace policies must address the needs and preferences of local employers. Such measures may include policies to promote drug- and alcohol-free workplaces. Accountability measures within recovery-supportive workplaces sometimes include drug testing and other measures to ensure safety in specific roles such as those involving operating heavy machinery. Although such policies might appear to disadvantage people with experience of OUD, evidence-based, transparent policies that address safety⁵⁰⁵ and productivity concerns

lessen employers' incentives to implicitly or explicitly discriminate against job applicants and workers on the basis of substance use disorders.

161. Individualized employment supports. Many people living with co-occurring mental illness and SUD experience particularly severe employment barriers. These individuals may benefit from individual placement and support (IPS) models that include individualized long-term supports. A strong body of research supports the effectiveness of IPS in assisting individuals with serious mental illness to obtain competitive employment.^{506,507} Many participants in these randomized trials experienced co-occurring substance use disorders. Although the specific elements of such interventions vary, the IPS model includes several core elements, including being open to anyone who wants to work and focusing on employment within the competitive labor market rather than within a sheltered or segregated setting. To avoid the stigma of prolonged joblessness, IPS focuses on rapid job search integrated with other service interventions. Participants receive individualized long-term supports which, if necessary, are integrated with addiction or mental health treatment. Within randomized trials that compare IPS with usual interventions, IPS participants display higher employment rates and higher incomes, and appear to experience higher quality of life.⁵⁰⁸
162. Addressing obstacles to education and employment. Structural barriers exist that prohibit individuals in recovery from returning to education or gaining employment. One method to address this is through the use of scholarships that help pay for school or vocational training, in conjunction with mentorship while in school. Programs to support students that are at risk of dropping out of school, who share many of the challenges experienced by students recovering from substance abuse, have proven effective. For example, two randomized controlled trials have shown that the Accelerated Study in Associate Program – through academic, personal, and financial support – is effective at improving the graduation rate among low-income students that would otherwise be at increased risk of not completing their degree.^{509,510,511} Separately, “Ban the Box” is a program that addresses barriers to entering the workplace and has benefited individuals with lived experience in the criminal justice system.⁵¹² These programs prohibit prospective employers from inquiring about an applicant’s criminal history on an initial job application; the term refers to the box that individuals are sometimes asked to check on an application as to whether they have a criminal record. Within the Communities, a modified version of “Ban the Box,” may balance the interests of employers and workers. For example, Lake or Trumbull County might prohibit requiring job applicants to supply information regarding arrests that do not result in convictions, misdemeanor convictions, or arrests for drug offenses that reflect personal use rather than more serious infractions.⁵¹³
163. Within the Communities, multiple efforts have been initiated to reach out to the business community. Operation Resolve is a program operated by Leadership Lake County, the Lake County ADAMHS Board, and the Lake County Opiate Task Force, which provides presentations to employers on substance misuse.^{514,515} Within Trumbull County, the ASAP Coalition works with local employers and the Chamber of Commerce to address barriers for individuals with SUD to both gaining and remaining in employment.⁵¹⁶ Additionally, the COMPASS Family and Community Services organization offers job training and placement through the Workforce Development program.⁵¹⁷
164. Components of abatement interventions. Vocational rehabilitation programs should be supported within Lake and Trumbull Counties. An effective jobs and vocational training program should include jobs training and placement services specifically deployed for individuals living with OUD. Additionally, consideration should be given to expanding job opportunities for all residents of the Communities to meet local needs created or worsened by the opioid epidemic. Programs should incorporate skill assessment and training, linkage with education and support, mentorship, and problem solving and coping skills in order to respond appropriately to workplace stressors.

165. In conclusion, an effective response to the challenge of OUD must include job opportunities and vocational training for members of the Communities. These efforts must include vocational services within substance use disorder treatment and related specific services for individuals living with OUD. These efforts should also include broader initiatives to serve all community residents to meet local needs created or worsened by the opioid epidemic.

D. Mental Health Counseling and Grief Support

The goal of this remedy is to ensure that mental health services, including counselling for individuals with mental illness as well as the bereaved, are available to all who may be in need within the Communities. This is important because historically these services have not always been readily available within the Communities, and yet the opioid epidemic has created unprecedented demand for such care.

166. The opioid epidemic has resulted in a high number of deaths among young people in Lake County and Trumbull County, which has impacted the mental health of individuals within the Communities. In addition to the pain of losing a loved one, addiction and trauma further complicate the grieving process. Grief support is necessary to help bereaved family members deal with questions that may include “Why did the person die from an overdose?” “Did the person intend to die?” and “Was the death preventable?”⁵¹⁸ Death of a loved one from an overdose may be especially difficult to process because of “disenfranchised grief,” resulting from lack of societal acknowledgement and support of a bereaved person’s loss.⁵¹⁹ Such disenfranchisement may be partly driven by stigma, including attitudes ultimately internalized by the bereaved that blame the decedent or their loved ones for the death.⁵²⁰ Of course, grief is but one of many potential psychological impacts of the opioid epidemic on loved ones of those with OUD; friends and family members may also experience depression, dysthymia, anger, anxiety, post-traumatic stress, or other psychological sequela.
167. As discussed elsewhere in this report (Section 4A and Section 4C), children have also been uniquely affected by the epidemic and unfortunately, many children in the Communities have suffered adverse psychological sequela. Because of this, they too are in need of expanded, state-of-the-art mental health services. Children that have been exposed to trauma, such as parental substance abuse, separation, or death, can have difficulty in school due to problems thinking, learning, and concentrating; trust issues or difficulty forming attachment; lack of impulse control; or behavioral issues such as fighting or running away.⁵²¹ Depression and anxiety also manifest differently in children than they do in adults, and may include symptoms such as irritability, changes in eating or sleep patterns, and self-injury or self-destructive behavior.⁵²²
168. One way to classify childhood trauma associated with the opioid epidemic are through adverse childhood experiences (ACEs), such as emotional neglect, loss of a parent or substance abuse within the household, that increase the likelihood of subsequent mental and physical health problems.⁵²³ Specifically, ACEs disrupt neurodevelopment which results in socioemotional and cognitive impairment; this impairment results in maladaptive behaviors (e.g., the adoption of risky behaviors such as substance abuse) and later the development of disease, disability, or social problems.⁵²⁴ A 2014 study of ACEs experienced by West Virginia adults found that nearly one in three adults experienced substance use in their childhood homes.⁵²⁵ The same analysis reported a dose-response relationship between the number of ACEs and depression; where one-fifth of adults that had one ACE also had depression, nearly half of adults with four or more ACEs reported depression. Trauma-informed mental health care can address some of these vulnerabilities by promoting coping and adaptive behaviors key to early neurodevelopment and the prevention of future morbidity and substance use. Additional protective factors to address ACEs are discussed in Section 1D and Section 4B.
169. Addressing mental health needs within the Communities is important to prevent future opioid use and to address harms caused by the opioid epidemic. As noted throughout this report (e.g., Section 1A and Section 2D), expanding services for pain management – including mental health counseling – is essential to reducing demand for opioids. Chronic pain and mental health disorders have a bidirectional relationship, where pain can worsen mental health, and vice-versa.⁵²⁶ A population-based study of randomly selected adults, found that study participants with neck or back pain were 2.5 times more likely

to experience depression within the following 12-months.⁵²⁷ Conversely, participants who were pain-free and had depression at the start of the study were four-times more likely to develop pain within 12-months than were participants who did not have depression at baseline. However, there are multiple barriers, including stigma, to accessing mental health treatment. A 2018 study found that, among those who were unable to access mental health treatment, 38% reported cost and lack of affordability, 21% did not know where to go for services, and 20% did not have adequate health insurance coverage for mental health services.⁵²⁸

170. Similar to many other areas in the U.S., the Communities have a shortage of mental health services for low-income individuals.⁵²⁹ However, with sufficient resources, there are programs that the Communities can use to address exposure to trauma and violence among children via the school system. For example, the Handle With Care program in West Virginia improves communication and collaboration between law enforcement, schools and childcare agencies and mental health providers.⁵³⁰ The program also seeks to connect families, schools, and communities to trauma-focused mental health services. In particular, social workers embedded in schools are instrumental in delivering trauma-informed counseling and wraparound services to children and adolescents in the Communities.
171. Bereaved parents and family members often require additional support to process and address their “disenfranchised grief.” However, when they receive proper support in the years following a death due to substance use, many family members can attain “posttraumatic growth” following the traumatic event.⁵³¹ Such growth occurs when positive psychological change results from exceptionally challenging life events. Grief support is key to facilitating this growth, where bereaved family members can process the complex emotions of stigma, guilt, anger, shock, and grief among individuals with shared experiences or understanding. While support networks may not be beneficial for everyone, it is important to have facilitators or counselors that can reorient individuals who may be “stuck” replaying memories or emotions from the past and identify new possibilities in life moving forward.⁵³² Within the Lake County, the Lake-Geauga Recovery Centers provide Grief Support Groups, which are offered at no cost to parents, spouses, partners, children, siblings, or friends recovering from the loss of a loved one to drugs and/or alcohol.⁵³³
172. Cognitive Behavioral Therapy (CBT) is the most frequently used psychological intervention for adults with chronic pain. Such approaches seek to improve mental health and well-being by identifying and changing maladaptive thoughts, emotions, and behaviors. Randomized trials of CBT for pain patients indicate that CBT can produce significant improvement in chronic pain and functional limitations.⁵³⁴ Many patients also benefit from mindfulness-based stress reduction, and from acceptance-based therapies,⁵³⁵ such as Acceptance and Commitment Therapy, that combines acceptance and mindfulness to promote psychological adaptability and behavior change. Clinicians and mental health counselors who treat children can provide most effective care when they receive additional training to address developmental needs within a trauma-informed approach.⁵³⁶
173. Components of abatement interventions. The Communities should expand the availability of mental health counseling for individuals with chronic pain, children affected by the opioid epidemic, and bereaved family members. Grief support interventions should include a blend of support groups led by mental health counselors as well as one-on-one sessions with mental health professionals. Faith-based support groups may also benefit individuals and families in the Communities. Behavioral interventions for those with chronic pain include cognitive behavioral therapy and acceptance-based therapies, and professionals should be included on multidisciplinary pain management teams.

174. In conclusion, abatement efforts within the Communities should provide for mental health counseling for children affected by the epidemic, individuals with chronic pain or current mental illness. Abatement should also include grief support services for bereaved family members. Providing mental health counseling within the Communities is necessary to address both the harms caused by the opioid epidemic and to prevent future opioid use from chronic pain and risk-taking or maladaptive coping behaviors among youth.

CATEGORY 4: ADDRESSING NEEDS OF SPECIAL POPULATIONS

Many groups of individuals have been uniquely affected by the opioid epidemic, in the Communities and beyond, including the homeless, pregnant women, children and adolescents, and families affected by the epidemic. Other important subpopulations, such as women⁵³⁷ or those living in rural areas,⁵³⁸ have also been impacted in unique ways. While some abatement remedies, such as naloxone distribution and training, generally need not be highly customized, there are other remedies that should be carefully designed with specific populations in mind.

A. Pregnant Women, New Mothers, and Infants

This abatement remedy focuses on pregnant women and new mothers who have chronic opioid dependence, opioid misuse or OUD, as well as infants born with neonatal opioid withdrawal syndrome (NOWS), a condition among newborns that is a consequence of in utero exposure to opioids. (NOWS is also sometimes referred to neonatal abstinence syndrome [NAS], although the latter is a less specific term that in certain contexts may refer to in utero exposure to other substances such as alcohol or tobacco.) As with other special populations, pregnant women, new mothers, and their newborns are important to consider because of the ways that abatement remedies should be designed to address their unique needs and vulnerabilities.^v

175. The opioid epidemic has severely impacted pregnant women, new mothers, and infants. Approximately 15% of commercially insured women and 22% of women on Medicaid filled an opioid prescription during their pregnancy between 2000 and 2011.^{539,540} This is important because the rate of NOWS has increased as opioid prescribing has increased. For example, in an analysis of hospital discharges from 2009 to 2012, the estimated rate of NOWS increased from 3.4 to 5.8 per 1000 hospital births nationwide.⁵⁴¹ A longer time horizon provides similar evidence, with estimates of the diagnosis of NOWS increasing from 1.2 to 8.0 per 1,000 live births between 2000 and 2014 nationwide; during this time period, some states experienced as large as a ten-times increase.⁵⁴²
176. Both SAMHSA and the American College of Obstetricians and Gynecologists (ACOG) have provided similar recommendations for targeting and treating pregnant women and neonates impacted by the opioid epidemic, including with respect to prenatal screening for opioid use among women who are pregnant, MAT treatment for pregnant women with OUD, neonatal care for neonates born with NOWS, and residential transition programs for pregnant women and new mothers with OUD who have limited social supports.^{543,544} Though individual models may differ for the immediate and long term care of children and mothers affected by opioids, generally the most successful models incorporate: (1) dyadic or family-centered models, that provide direct care for both children exposed to opioids and medical and addiction care to help parents maintain recovery; (2) comprehensive pediatrics programs, with multidisciplinary and long-term care for children, linked with care for parents as needed; and (3) specific developmentally-focused pediatrics programs, that provide longitudinal developmental evaluations and support.⁵⁴⁵ Researchers and health providers have emphasized the importance of maintaining family relationships (i.e., family-centered treatment), which improves health and socioemotional outcomes for women and children.^{546,547}
177. Prenatal screening. SAMHSA and ACOG strongly recommend screening pregnant women for substance use disorders including OUD. ACOG specifically recommends universal screening as part of obstetric prenatal care visits, and both suggest using validated screening tools such as the National Institute on Drug Abuse's Quick Screen or Substance Use Risk Profile–Pregnancy (SURP-P).⁵⁴⁸ Both organizations also suggest screening be incorporated into an algorithm such as SBIRT or STIR as discussed in Paragraph

^v Additional testimony and evidence regarding these populations is provided by Dr. Nancy Young in her expert report; I incorporate some of this evidence into my Redress Models for pregnant women, new mothers and infants.

#189.⁵⁴⁹ The decision to initiate MAT upon an initial visit, as compared with referral for follow-up care, should be informed by a number of factors, including the context of the visit, stability and preferences of the patient, and availability and likelihood of suitable follow-up.

178. MAT treatment. SAMHSA and ACOG suggest pregnant women with OUD be treated with MAT. This is partly due to concerns that other treatment approaches, such as abstinence, pose an increased risk of fetal injury or demise. MAT treatment should focus on the provision of buprenorphine and methadone, rather than naltrexone, since there is less information on how naltrexone may impact fetal development. Such treatment is important in custodial as well as community settings, and fortunately, the Maternal Opioid Medical Support (MOMS) Program provides MAT, medical, and behavioral health care to postpartum women.⁵⁵⁰
179. Neonatal care. Expression of NOWS is widely variable, though long-term complications may include poor neurological and motor development.⁵⁵¹ Infants at risk of presenting with NOWS may require specialized care such as hospitalization within a neonatal intensive care unit, although it is difficult to predict the severity of withdrawal symptoms a given newborn is likely to have.⁵⁵² For example, Lily's place is one program in West Virginia, where babies with prenatal drug exposure who need additional treatment are discharged to Lily's Place from the ICU for observational, therapeutic and pharmacologic care to ease withdrawal symptoms.⁵⁵³ Lily's Place offers care in a community-based setting, using a team of peer recovery coaches, social workers, and health professionals that focus on preparing the infant to rejoin their families.
180. Residential transition programs. Pregnant women and new mothers also need stable environments for their own health, their babies' health, and for the best chance for positive treatment outcomes. A stable environment includes long-term housing, child-care, access to transportation, all within a family-oriented and supportive environment. Some pregnant women with OUD will require residential treatment because of limited economic capital and/or serious medical illness or behavioral health needs. When possible, it is important to include additional members of the family (e.g., partner) in treatment or residential programs, because when family members progress through treatment, the short- and long-term outcomes for children and parents improve.⁵⁵⁴ In addition to recovery housing for families, additional step-down and transitional housing services need to be expanded in the Communities.
181. In Lake County, the Lake-Geauga Recovery Centers operates Nevaeh Ridge, a six-bed facility for pregnant women and women with children aged five years and under, who have SUD and receive outpatient services at Lake Geauga Recovery Centers' Mentor Outpatient office.⁵⁵⁵ Services provided include pre-natal care, individual and intensive group counseling, dual-diagnosis services, vocational training, and workforce preparation.
182. Psychosocial supports. The majority of pregnant women and new mothers with OUD have experienced significant traumas, such as a history of sexual assault and/or domestic violence.⁵⁵⁶ Pregnant women and new mothers must be provided with psychosocial supports to cope with past traumas, the life-changes of a newborn, and progression through recovery in order to successfully remain in recovery. Women should also be taught life-skills and provided with job skill and education courses. Wrap-around services for pregnant women, new mothers, and infants such as, childcare for appointments, assistance with basic needs, and case management are crucial for treatment retention and success. Family navigators may also be used to provide intensive case management to each family, through a family needs assessment, individualized plan, and providing guidance through the available services and resources.
183. Components of abatement interventions. Existing efforts for universal prenatal screening and specialized care for pregnant women, new mothers, and infants should continue to be supported and expanded where

needed. Pregnant women who are diagnosed with OUD must receive adequate treatment and medical care as soon as possible, with continued treatment after they deliver. Additionally, all infants born exposed to opioids should receive developmental support through special education beginning immediately after birth. Pregnant women with OUD and new mothers of infants exposed to opioids should receive intensive biopsychosocial services and, if needed, housing. Lower intensity biopsychosocial services should be offered following the period of intensive biopsychosocial services.

184. In conclusion, abatement programs in the Communities should include resources for pregnant women, new mothers, and neonates impacted by the epidemic. Such resources are described more thoroughly by Dr. Nancy Young in her expert report, but generally should include: services to identify and treat pregnant women with OUD as early as possible; longitudinal services to support women and address modifiable risk factors throughout their pregnancy; clinical and behavioral interventions in the peri- and post-partum period; hospital and child welfare resources to comply with the Child Abuse Prevention and Treatment Act to ensure a plan of safe care is implemented for the infant and family or caregiver before the infant is discharged from the hospital; and follow-up services to optimize care for the mother-child dyad following hospital discharge, including the required developmental assessment for early intervention if the child is placed in out-of-home care. When possible, the entire family should receive treatment and family-strengthening interventions in order to promote long-term socioemotional health.

B. Adolescents and Young Adults

The goal of this remedy is to address the direct impact of opioid use, addiction, and overdose on children, adolescents, and young adults in the Communities, including prevention programs that delay initiation or escalation of opioid use as well as screening and treatment programs that are customized to the unique needs of these special populations.

185. Children and adolescents are uniquely vulnerable to the consequences of non-medical opioid use, and as the opioid epidemic has flourished, many children and adolescents have been exposed. In 2005, approximately 1.7 million (6.9%) of adolescents aged 12 to 17 years nationwide reported past year non-medical use of pain relievers and 166,000 (0.6%) fulfilled formal diagnostic criteria for OUD.⁵⁵⁷ Fortunately, rates of non-medical use of opioids have declined, although even in 2018, 695,000 (2.8%) of adolescents reported such past year non-medical opioid use and 108,000 (0.4%) had OUD.⁵⁵⁸ Such use has occurred at high rates within the Communities.
186. The American Society of Addiction Medicine recognizes adolescents (aged 11-21 years), as a special population of interest with respect to substance use disorders.⁵⁵⁹ Not only has early initiation of drug use been strongly associated with a constellation of adverse consequences, such as poor peer and familial relationships, and entanglements with the juvenile justice system,⁵⁶⁰ but the ongoing brain development in adolescents during this period of time makes them highly vulnerable to substance use disorders.⁵⁶¹ Because of their vulnerability and future potential, prevention and early detection of substance use disorders in youths should be heavily prioritized to minimize the short- and long-term consequences associated with drug use at an early age.
187. Several school-based or family-based prevention programs have successfully delayed or prevented initiation or escalation of drug use in youths.^{562,563,564} For example, the Life Skills Training (LST), a widely used school-based module, has been demonstrated in several controlled studies to reduce substance use amongst adolescents.⁵⁶⁵ The impact of LST may be enhanced when coupled with the Strengthening Families Program (SFP), a family-based intervention designed to develop and support family bonds and communication. Greater investment should be made in the continued dissemination, implementation and evaluation of these and other evidence-based programs that are focused on primary prevention through education of broad populations regarding the nature of OUD, risks of non-medical opioid use, and availability of treatment and recovery support.
188. Treatment for adolescents with substance use disorder requires a unique approach and should be delivered by individuals with specialized training in the care of this population. For example, unlike older adults who have often spent years coping with substance use accompanied by a deterioration in psychosocial domains such as loss of job or family, adolescent users tend to present at treatment after only a few years of addiction. In contrast to adults with substance use disorders, adolescents' drug use is often driven by different factors (e.g., familial discord), may be subject to different environmental influences (e.g., peer effects), and may compromise psychological and social development.⁵⁶⁶
189. A subset of adolescents participating in prevention programs will be identified as high risk. These individuals should be further evaluated through formal screening. While some have advocated for Screening, Brief Intervention, and Referral to Treatment (SBIRT) as a method of formal screening, SBIRT was developed primarily for alcohol use disorder and concerns with its application to opioids have been raised. For example, some evaluations of SBIRT have failed to demonstrate meaningful increases in abstinence and the effect in positive studies is often modest.⁵⁶⁷ In addition, SBIRT is predicated upon the availability of follow-up treatment and the motivation of the individual to seek it, and the "brief intervention" of SBIRT was designed for behavioral treatments, which overlooks FDA-approved

pharmacotherapies for OUD. Because of this, Screening, Treatment Initiation and Referral (STIR) has been proposed,⁵⁶⁸ and demonstrated to achieve better outcomes than SBIRT in at least two randomized trials, one focused on tobacco dependence⁵⁶⁹ and the other on OUD.⁵⁷⁰

190. Use of MAT is recommended for adolescents with severe opioid use disorders. Buprenorphine and naltrexone may provide more suitable treatments for adolescents than methadone, since these can be administered in office-based treatment settings. Furthermore, one of several evidence-based psychosocial therapies should be used simultaneously with MAT when treating adolescents with substance use disorders. One type of psychosocial therapy is family-based therapy, which aims to reduce the adolescent's drug use by involving the youth's family members in the treatment process. This mode of therapy facilitates the development of emotional support and communication strategies in order to address issues such as antisocial behavior or dysfunctional family interactions.
191. In Trumbull County, the ASAP Coalition provides training, education, and prevention activities for families and children in schools.⁵⁷¹ Additionally, the ASAP Coalition utilizes results from the PRIDE survey, which identifies drug trends among elementary, middle, and high school students.^{572,573,574} In Lake County, outreach and prevention education are also offered through the ADAMHS Board, in partnership with the Lake County Opiate Task Force.^{575,576,577}
192. Components of abatement interventions. School-based prevention interventions should be expanded in Lake County and Trumbull County, and target adolescents in areas identified as having high rates of opioid burden, including overdose deaths and misuse rates. These programs should also identify adolescents at a high risk of opioid misuse or OUD for further screening. The estimates provided for this category are based on needs for screening rather than direct treatment; a subset of those screened will require pharmacologic and in some cases, inpatient, residential or intensive outpatient OUD treatment. The costs of such interventions are subsumed elsewhere (e.g., Section 2B, "Treatment for Opioid Use Disorder").
193. In conclusion, abatement programs in the Communities should include resources to reach at-risk children and adolescents through school and community-based youth programs. In addition to screening and primary prevention programs to teach and reinforce positive life skills, resources should also be committed to the care of children and adolescents with non-medical opioid use or OUD, which may require expansion of personnel with customized expertise in this area, as well as resources to support the expansion of both pharmacologic and non-pharmacologic treatment and recovery services.

C. Families and Children

The goal of this remedy is to improve the resources available to support children in the Communities who have been orphaned by the epidemic, as well as to assist children and their families who have otherwise been impacted and who may be served through child protective services. As with Section 4A, additional testimony and evidence are provided by Dr. Nancy Young in her expert report, which I also incorporate for certain populations in the Redress Models for this section.

194. The opioid epidemic has severely impacted many families, and at times, forced children to be separated from parents and placed in foster care. In 2017, there were nearly 443,000 children in foster care in the U.S., an increase of 46,000 children since 2012.⁵⁷⁸ Much of this increase is attributable to the opioid epidemic.⁵⁷⁹ Of the 273,000 children that entered foster care in 2016, over 92,000 (34%) were placed in out-of-home care wherein parental substance use was reported as a factor in the reason for removal.⁵⁸⁰ However, states vary in reporting on this variable and these data are considered an undercount of the prevalence of substance use among child welfare cases nationwide.^{581,582,583} Vastly more children – as many as one in eight – live in a household with one or more parents who have a history of past year substance use disorder.⁵⁸⁴
195. While the precise number of foster care placements that are directly due to opioids is unknown, a recent mixed-methods study commissioned by the U.S. Department of Health and Human Services provides additional context.⁵⁸⁵ Geographic regions of the country with higher rates of overdose deaths and drug-related hospitalizations also have higher child welfare caseloads, as well as more severe and complex child welfare cases. In addition, many key informants reported worsening conditions, such as overdose deaths and caseload numbers, between 2015 to 2017. The report also identified many barriers to treatment of impacted families, including misunderstanding and mistrust of MAT, piecemeal substance use assessments, shortages of family-friendly treatment, and an increasing shortage of foster care homes. The report concluded that while these findings may not represent every geographic region or state, they nevertheless suggest how the opioid crisis has taken an unusual toll on an already strained child welfare system.
196. Children entering the foster care system, including those whose entry has been driven by the opioid epidemic, have both medical and non-medical needs. Federal and state governments often provide support to guardians of foster children for non-medical needs such as food, clothing, and housing. Many children in foster care also have special health care needs, given the high prevalence of chronic medical, developmental, and mental health problems, most of which predate placement in foster care.⁵⁸⁶ Lastly, approximately 21-23% of children exiting foster care are adopted.⁵⁸⁷ Though some adoption costs are offset with government subsidies, the adoption process can nevertheless impose a heavy economic burden on some families.
197. Child protective services (CPS) includes a variety of interventions that are undertaken by state agencies charged with optimizing the health and welfare of otherwise vulnerable infants, children, and adolescents. Such services include the investigation of reports of child abuse or neglect as well as the delivery of services, such as specialized case management and multisystemic or other family-based therapy, to support children and families where abuse or neglect has taken place or is likely. One such approach is Parent-Child Interaction Therapy (PCIT), an evidence-based and family-centered treatment approach that supports the development of parenting skills while reducing negative parent-child interactions. There is a broad evidence-base supporting the value of PCIT in achieving a host of positive outcomes including decreased parental stress and use of corporal punishment and increased parent-child interactions.⁵⁸⁸ Both PCIT and, more broadly, CPS are based on several underlying principles including a recognition that a

safe and permanent home is the best location for children to be raised and that most parents want to be good parents to their children.⁵⁸⁹

198. In Lake County, the Kinship Navigator Program aims to help grandparents and other family members who have custody of children due to another family member's substance use. This program offers caregivers personalized information, as well as referrals to other supports and resources in Lake County.⁵⁹⁰ In Trumbull County, many grandparents and other kinship caregivers are linked to support and information through the ASAP Coalition.⁵⁹¹ Across Ohio, virtual support groups are increasingly common and found through the Ohio Grandparent/Kinship Coalition.⁵⁹²
199. Components of abatement interventions. CPS agencies in Lake County and Trumbull County should be adequately funded to deal with cases related to opioid use and prioritize permanency for children impacted by the epidemic. Children who enter or are in foster care or are adopted due to familial opioid use or overdose must receive adequate medical care and comprehensive social services to address their needs. Adoption costs and adoption-related expenses of children who were adopted due to familial opioid use or overdose should be covered. Children in foster care or who are adopted and qualify for PCIT should receive it.
200. In conclusion, abatement programs in the Communities should include resources to support the needs of children who have been orphaned by the epidemic or who have lost a parent, whether or not they have entered the foster care system. In addition, abatement remedies should include resources, including intensive case management and access to therapy, to support the needs of children and adolescents who may have entered child protective services or otherwise come to the attention of social services organizations due to the opioid epidemic.

D. Homeless and Housing Insecure

The goal of this abatement remedy is to focus on individuals with OUD in the Communities who may be homeless or housing insecure. In order to be successful, abatement programs within the Communities must be deployed to address the unique and pressing clinical and public health needs of these often marginalized populations.

201. Homelessness and housing insecurity are traumatic experiences that threaten individuals' economic, psychological, social, and spiritual wellness. In 2019, a point-in-time count estimated that 10,345 individuals were homeless in Ohio,⁵⁹³ yielding a rate of 88.5 per 100,000 Ohioans.⁵⁹⁴ However, for every individual that is homeless many more may have "housing insecurity," or problems with the affordability, safety, quality or long-term stability of their housing.^{595,596} Once an individual is homeless, it is difficult to re-enter the workforce and attain stable housing. Many homeless individuals also have acute and chronic physical health conditions and mental illness that require specialized treatment. However, financial and other barriers often make it impossible to receive such care, posing stressors that increase the risk of substance use disorders. For example, one national study found that among those who were homeless and reported substance abuse in the previous year, 75% also had a mental illness.⁵⁹⁷
202. Substance use disorder is among the leading causes of homelessness in the country.⁵⁹⁸ A survey of homeless individuals in San Francisco found that nearly one-in-three reported opioid misuse in their lifetime.⁵⁹⁹ Homeless individuals with OUD are also more likely to become chronically homeless and have a higher risk of overdose and mortality.⁶⁰⁰ A Boston study found opioid overdoses to be the leading cause of death among homeless individuals; compared to those that were stably housed, homeless individuals were nine-times more likely to die of overdose.⁶⁰¹ Nationally, opioids are involved in 61% of overdose deaths among those that are stably housed, however, opioids are involved in 81% of overdose deaths among those that are homeless.⁶⁰²
203. Prescription drug and opioid misuse are particularly high among homeless youth. A survey of 451 homeless youth found that half reported prescription drug misuse in their lifetime.⁶⁰³ Of those that misused prescriptions in the past month, one-in-four used prescription opioids alone and one-in-three used heroin. This was associated with an increased risk of future substance use, poor self-reported health, and risky sexual behaviors. The survey also found a higher risk of post-traumatic stress disorder (PTSD), depression, and suicidal ideation among homeless youth that misused prescription drugs.
204. The causes and effects of homelessness are complex and require multilayered interventions that focus on social support, trauma-informed approach, and personal choice.⁶⁰⁴ Homeless individuals with OUD are often ineligible for many housing programs due to their substance use. However, housing and support are critical to providing an environment where individuals can focus on recovery. A study of homeless veterans, many with OUD, reported that social support was crucial to maintaining housing and recovery.⁶⁰⁵ Given the high prevalence of trauma among homeless individuals with OUD, using a trauma-informed approach and building trust are key to engaging them in care.⁶⁰⁶
205. Treatment and housing programs vary in services offered, sobriety requirements (e.g., low-barrier), and integration with the community (e.g., light-touch). Low-barrier models have been gaining support for their effectiveness in retaining clients in care since they do not require sobriety, and in doing so, account for the fact that relapse is common among homeless individuals with substance use disorder.⁶⁰⁷ Because individuals are not penalized for relapsing, trust and rapport are built, which opens the door for engaging them in treatment. A low-barrier program in New York found that clients were more likely to continue their MAT as prescribed for OUD three-years after initiating the program.⁶⁰⁸ The Homeless Multidisciplinary Street Team, a mobile outreach program in California, included a team of specialists

that sought out the highest-cost members of the homeless community (e.g., those who are repeatedly hospitalized or incarcerated) to assist them in receiving housing and other treatment in 2016.⁶⁰⁹ This program resulted in savings between \$103,000 to \$259,000 for the city of Santa Monica by decreasing the health and public service utilization among high-cost homeless individuals. Additionally, “permanent supportive housing,” or housing with support, is another intervention that addresses chronic homelessness by integrating housing with health care, intensive case management, legal services, social service advocates, and occupational therapy. The U.S. Department of Housing and Urban Development estimates that investments in permanent supportive housing have reduced chronic homelessness by 20% between 2007 and 2019.⁶¹⁰

206. Recovery housing is also an important component of care for some people with OUD. The National Alliance for Recovery Residences (NARR) defines four levels of recovery housing ranging from self-funded, peer-run, residential facilities where individuals can stay indefinitely (Level 1) to residential facilities that also serve as clinical treatment centers (Level 4).⁶¹¹ As explained by one public health officer: “Who we spend our time with, where we go, and the things we surround ourselves with all impact who we are and the decisions that we make. Many times, people in early recovery have to give up everything they’ve known... because those people, places, and things put them at risk for relapse or continued use. Early recovery can be painful and isolating. Recovery housing can fill that void with a safe place, compassionate people, and a life full of purpose and fun that doesn’t involve alcohol or drugs.”⁶¹²
207. As with peer recovery coaches, evidence examining the effect of recovery housing on outcomes such as drug and alcohol use, employment and psychiatric symptoms, while limited, suggests beneficial effects.⁶¹³ However, concerns have also been raised regarding substandard or outright fraudulent services being provided by some recovery houses. A March 2018 report from the U.S. Government Accountability Office (GAO) examining this matter in five states underscores both the potential promise of recovery housing as well as the importance of adequate state regulatory oversight of their practices to ensure the prevention of exploitative or outright fraudulent housing practices.⁶¹⁴
208. Components of abatement interventions. Efforts to address the needs of individuals with OUD who are homeless or housing insecure should be supported and expanded upon within Lake County and Trumbull County. In particular, Permanent Supportive Housing that provides wraparound services for homeless individuals with OUD should be implemented in the Communities. Additional needs of individuals with OUD who are homeless or have housing insecurity must be addressed as part of any abatement program and are included elsewhere in this report. These include: access to comprehensive, longitudinal OUD treatment (Section 2B); transitional housing for those newly released from incarceration (Section 3B); and treatment and housing services for pregnant women and new mothers (Section 4A).
209. In conclusion, abatement programs in the Communities should include resources to reach homeless individuals and those who are housing insecure. By providing social support and focusing on the physical and mental health of these individuals, the Communities can reduce the economic and public health impact of the opioid epidemic. Resources should focus on increasing treatment services, personnel and housing for those that are homeless or housing insecure.

E. Individuals with Opioid Misuse

This abatement remedy focuses on individuals who misuse opioids. This category is important because many individuals engage in such misuse, and they are at elevated risk for a number of harms from opioids, including the development of OUD and overdose death.

210. Opioid misuse is defined by the National Institute on Drug Abuse as “taking a medication in a manner or dose other than prescribed; taking someone else’s prescription, even if for a legitimate medical complaint such as pain; or taking a medication to feel euphoria (i.e., to get high).”⁶¹⁵ In contrast to OUD, which has formal diagnostic criteria according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), opioid misuse is more common and encompasses a broader continuum of behaviors. It is important to identify individuals with opioid misuse because they are at increased risk of opioid-related adverse events.
211. An estimated 11.4 million Americans, or 4.2% of the total population, reported misuse of prescription opioids or heroin during the past year based on 2017 data derived from the National Survey of Drug Use and Health (NSDUH).⁶¹⁶ While this represents a modest decline from 2015, during which 12.7 million people were estimated to have engaged in past year opioid misuse, the numbers nevertheless remain staggering. Of these 11.4 million individuals, 97.2% engaged in past year misuse of prescription opioids, while 7.8% engaged in misuse of heroin and 4.9% engaged in misuse of both prescription opioids and heroin. Among adults who misused opioids in 2015 who did not have an OUD, approximately two-thirds of cases reported the reason for such misuse was the relief of pain, highlighting the overlap of chronic pain with non-medical opioid use as well as the opportunities to address both simultaneously through well-designed abatement remedies.⁶¹⁷
212. As many as one-third of individuals misusing opioids nationwide report that the source of their opioids was a single prescriber,⁶¹⁸ an indication that the health care system, including high prescribing clinicians, continues to play a role in fostering the epidemic.^w More than one-half of those misusing opioids report their source as a friend or relative, a reminder of the continued diversion of opioids that also commonly occurs, although here too, the most common source of opioids among these friends or family members remains a licensed prescriber.⁶¹⁹ The large oversupply of opioids in these settings supports the use of interventions such as prescription “caps” that states and some payers are increasingly using to reduce the volume of opioids prescribed for short-term use,⁶²⁰ as do several studies indicating that the likelihood of an individual converting to chronic opioid use is significantly greater among individuals receiving greater doses or durations of opioids on their first fills.^{621,622,623}
213. In contrast to patients who are using opioids fully as directed under the care of a licensed prescriber, which still poses unacceptably high risks in many patients currently receiving them, patients with opioid misuse should be identified and targeted for early intervention so as to avert their potential transition to OUD or overdose. Methods to identify and address these patients include both the routine clinical use of the data from OARRS and clinical interviewing. Clinical interviewing is useful not only to screen for potential misuse but also to explore motivations for such and to address underlying issues, including sub-optimally treated pain, depression or other behavioral health factors that may be driving such behavior. Once identified, such patients should receive more intensive clinical monitoring, psychosocial interventions, pain management, and in some cases, transition to partial opioid agonists such as buprenorphine or tramadol.

^w By contrast, 1.5% of those with opioid misuse report their source as from more than one doctor, again attesting to the relatively small contribution opioid shoppers make to the epidemic. (Chang HY, Murimi IB, Jones CM, Alexander GC. Relationship Between High-Risk Patients Receiving Prescription Opioids and High-Volume Opioid Prescribers. *Addiction*. 2018;113:677-686.)

214. Components of abatement interventions. The components of this abatement category are subsumed in other abatement interventions that I discuss including Health Professional Education (Section 1A), Patient and Public Education (Section 1B), Safe Storage and Drug Disposal Programs (Section 1C), and interventions targeting Adolescents and Young Adults (Section 4B).
215. In conclusion, abatement programs in the Communities should include resources devoted to addressing the substantial minority of individuals who misuse opioids. Clinicians should be trained to routinely evaluate patients for such practices, OARRS data should be increasingly integrated within health systems and electronic medical records, and interventions should be deployed to decrease the volume of opioids prescribed, which in turn will decrease the incidence of misuse. Once opioid misuse has been identified, greater clinical resources should be devoted both to addressing opioid misuse directly as well as evaluating and treating potential contributory factors ranging from comorbid social stressors or mental illness to untreated or undertreated chronic pain syndromes.

VI. MEASURING THE SUCCESS OF ABATEMENT EFFORTS

216. The Communities are already undertaking many evidence-based abatement interventions that reflect the overarching principles, as well as strategies, that I outline above. For example, the Communities have active, although resource constrained, drug courts; the state and local health departments have worked to distribute naloxone and train individuals from the Communities in its use (e.g., Project DAWN); and there is a program for pregnant women and new mothers with OUD (e.g., MOMS). Key partners include community drug prevention coalitions such as the ASAP Coalition, and treatment providers such as: Meridian Health; Signature Health; Crossroads Health; Lake-Geauga Recovery Centers; the Lake County Alcohol, Drug Addiction, and Mental Health Boards; and the Trumbull County Mental Health and Recovery Board.
217. Data – and measurement – is vital to these efforts, a fact that is affirmed by the U.S. Department of Health and Human Service’s Five-Point Opioid Strategy, which includes “Better Data” as one of the five key strategies to address the crisis.⁶²⁴ Without such information, the Communities are “flying blind,” no better off than an airplane pilot without access to the plane’s instrument panel. Section 1F outlines in detail the evidence base supporting surveillance and the uses of such data.
218. The core measures in the Communities ultimate abatement plan should represent essential outcomes selected because of their linkage to abatement goals and their ability to capture key consequences of improved prevention, treatment, and recovery services. Each measure should be assessed on a quarterly, biannual, or annual basis, understanding that the more frequent an assessment occurs, the more rapidly such information can be used to iteratively inform further abatement. Such measures should provide a means of performing high-level evaluation of the global effects of abatement efforts on central outcomes of vital clinical and public health importance. Examples of potential measures include:
- Rates of non-fatal opioid overdose
 - Prescription opioid overdose death rate
 - Heroin/illicit fentanyl overdose death rate
 - Emergency Department visits or hospitalizations related to opioids
 - Percent of 10th graders reporting non-medical opioid use
 - Rate of infants born with neonatal abstinence syndrome
 - Rate of complications associated with opioid use

During the coming years, as additional resources are invested in reducing the oversupply of opioids and attendant harms, there will also be opportunities to continue to enhance, collate, link and centralize measures with others that capture other dimensions of the epidemic, including: the accessibility and quality of both pain and OUD treatment; treatment delivery within the criminal justice system; and the performance of the care delivery system for other populations, such as the commercially insured, for which the state or county may not serve as payer.

VII. ESTIMATED IMPACT OF PROPOSED ABATEMENT REMEDIES

219. There is intuitive scientific appeal in using randomized experiments to assess the effectiveness, and comparative effectiveness, of different interventions to reduce opioid-related morbidity and mortality. However, such investigations are impractical, and often unethical as well.⁶²⁵ As a result, policy-makers and other stakeholders must rely upon observational evidence that is prone to shortcomings. For example, the effect of an intervention such as a naloxone law may be delayed, obfuscated by other contemporaneous policy changes, or associated with unintended effects that diminish its ultimate welfare impact. Indeed, many studies examining the impact of various abatement remedies have assessed multiple simultaneous interventions, such as an intervention to reduce opioid oversupply that combines educational outreach to clinicians with clinical decision support instituted within electronic medical records. These challenges underscore the importance of continued study by clinicians and public health experts, as well as investments such as the National Institutes of Health's HEAL Initiative.⁶²⁶
220. While some may argue that "further research is needed," there is already a vast scientific evidence base to support the abatement interventions discussed herein. For example, there is unequivocal evidence of the benefits of treatment for OUD, the life-saving potential of naloxone, and the value of investments made in children and families impacted by substance use disorder. While using this evidence to estimate the expected impact of specific interventions within specific communities is prone to uncertainty, some general conclusions regarding abatement impact can be drawn.
221. First, the impact of treatment for OUD on reducing OUD rates over time, which represents one of the most important, and costly, interventions prescribed in this report, has been well described. For example, in a systematic review and meta-analysis of MAT, the pooled all-cause mortality was 0.92 (95% confidence intervals [CI] 0.79-1.04) per 1,000 person-years among individuals during treatment, 1.69 (CI 1.47-1.91) among those after treatment and 4.89 (CI 3.54-6.23) among those who were untreated.⁶²⁷ In another careful and comprehensive systematic review and meta-analysis, Sordo and colleagues found that the pooled all-cause mortality rates were 11.3 and 36.1 per 1,000 person-years in and out of methadone treatment (unadjusted out-to-in rate ratio 3.20, CI 2.65-3.86), and 4.3 and 9.5 in and out of buprenorphine treatment (2.20, CI 1.34-3.61).⁶²⁸ In other words, treatment for OUD reduced the likelihood of death by at least *a half* in these analyses.
222. Second, different interventions will have different impacts that will vary based upon the local context and magnitude of unmet need. In addition, the time horizon to see an impact from abatement efforts varies. Some investments, such as those for naloxone or treatment expansion, may produce an immediate impact on the Communities, whereas others may have medium-term (e.g., drug courts, transitional housing) or long-term (e.g., child and family services) effects that may be no less important to the Communities ultimate recovery.
223. Third, the return on investments from some programs can be quite profound. In other words, improving treatment uptake and use for OUD is not just the right clinical thing to do, it also makes good economic sense, in part because OUD has so many direct and indirect costs. For example, Ettner and colleagues⁶²⁹ and Gerstein and colleagues,⁶³⁰ have estimated at least a 7:1 return on investment when examining the economic benefits and costs of the treatment of alcohol and drug disorders using California treatment data.^x Similarly, an analysis of a naloxone distribution program in North Carolina, as described in Section 2E, estimated that, on average, for every dollar spent on the program, there was \$2,742 of benefit due to opioid overdose deaths avoided.⁶³¹ In a separate decision analysis from the University of San Francisco,

^x These analyses were not limited to those with OUD. While the reports nevertheless suggest the value of OUD treatment, including MAT, there is also a need for further research focused exclusively on OUD treatments rather than broader substance use disorders.

investigators estimated that providing naloxone to heroin users is robustly cost-effective, and possibly cost-saving, with one overdose death prevented for every 164 naloxone kits distributed.⁶³² Yet other work has examined potential savings associated with investments in harm reduction such as SSPs, suggesting that for every dollar invested in SSPs, at least six dollars are saved due to HIV prevention alone.⁶³³ A separate cost-effectiveness analysis of an SSP in New York City estimated that the program would result in a baseline one year savings to the government of \$1,300 to \$3,000 per client.⁶³⁴

224. Fourth, as noted in Paragraph #17, “the cost of doing nothing is not nothing.”⁶³⁵ The opioid epidemic has worsened over more than two decades, both nationally and particularly in the Communities, and for a long time, was hidden in plain sight. Fortunately, there is acknowledgement of the devastation that opioids have caused for many communities. In addition, a great deal of scientific effort has been expended to develop an evidence base regarding the approaches noted herein. This overwhelming evidence explains the strong scientific consensus regarding the importance of the abatement remedies proposed.

225. While further extrapolation is required to estimate the combined, community-level impact of interventions I propose, I believe that they can reduce cumulative opioid overdoses and opioid-related harms by 50% over fifteen years. This estimate is based on models that we⁶³⁶ and others^{637,638,639,640} have developed, as well as review and synthesis of additional assessments of many of the interventions proposed herein, ranging from Health Professional Education (Section 1A) to Harm Reduction interventions (Section 1E) to Distributing Naloxone and Providing Training (Section 2E).

VIII. POTENTIAL OBJECTIONS TO PROPOSED ABATEMENT REMEDIES

There is remarkable consensus among public health experts regarding the abatement remedies outlined above. Nevertheless, some might object to one or more of the proposed remedies on a number of grounds.

226. Enough is already being done. One argument is that there is already an enormous amount of effort being devoted to the epidemic in the Communities, as well as some signs that things are “turning around” locally. For example, prescription opioid volume continues to decline in the Communities, and despite a resurgence in opioid overdose death since 2020, overdoses were generally lower between 2018 and 2019 than previous years (Paragraph #21). While such arguments might have some appeal, they overlook the complexity of the epidemic, continued evidence of grave harms in the Communities and the fact that investments made thus far pale in comparison to the epidemic’s societal costs. For example, despite declines in opioid sales, prescribing rates remain far above pre-epidemic baselines. Similarly, the rate of overdoses in Lake County and Trumbull County increased in 2020, and there is no indication that supply of illicit fentanyl has been stopped. As noted throughout my report, there are vast gaps that remain in the treatment system, and many of the most damaging consequences of the epidemic, such as its effects on children, families and those with active addiction or a history of OUD, will endure for generations.
227. There may be unintended consequences. Concern has been raised regarding potential unintended consequences of efforts to address the epidemic, especially “supply-sided” interventions such as clinical guidelines that may reduce the volume of opioids used in clinical practice (Section 1A).^{641,642} It is theoretically possible that reductions in opioid prescribing may pose a burden for individuals in whom opioids are clinically appropriate, and thus, underscores the importance of multifaceted approaches to diminish this likelihood, including: investments in pain research; continued evidence generation and synthesis such as the activities undertaken by the CDC and professional societies, provider and patient education; insurance coverage and benefit redesign; and surveillance. Similarly, while arguments that constraining opioid oversupply “just pushes people to heroin” are over simplified,^y such concerns underscore the urgency of expansions in the treatment system to accompany supply-sided interventions reducing the flow of people from the general population into opioid use disorder.
228. We shouldn’t reward bad behavior. Variations on this argument include that people who are “running into trouble” should know better, or more abhorrently still, “three strikes and you are out.”^z These approaches to managing the opioid epidemic blame the victims and reflect classic stigmatizing language grounded in erroneous beliefs regarding the nature of addiction. No one chooses addiction any more than one chooses to have heart failure or multiple sclerosis.⁶⁴³ Such language overlooks this and conflates abuse, which is a behavior, with addiction, which is a disease. It also is hard to reconcile such views with the fact that, as established in the expert report by Dr. Anna Lembke, the majority of individuals with OUD developed it through receipt of opioids from the health care system. It is precisely this type of language, and persistent stereotypes regarding the nature of opioid dependence, misuse and addiction, that have slowed progress in addressing the epidemic over two decades, and that should be aggressively rebutted head-on as part of campaigns to educate the general public and health care providers regarding the nature of the epidemic.
229. MAT isn’t that effective and it is diverted. In fact, there is a substantial body of evidence regarding the effectiveness of treatments such as buprenorphine and methadone in retaining people in treatment, reducing illicit drug use, decreasing criminal activity and preventing overdose death.^{644,645} It is true that

^y There is not a zero-sum game between reducing prescription opioid oversupply and increasing heroin use. For example, see Compton WM, Jones CM, Baldwin GT. Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use. *New England Journal of Medicine*. 2016;374:154-63.

^z Such an argument was proposed by a city council member in a small town in Ohio, who argued that the use of Emergency Medical Services should be restricted among people who utilize such services for multiple opioid overdoses.

relapse among people with OUD is not uncommon, just as is the case with cancer, depression and many other chronic diseases. Similarly, while treatment failures occur with MAT, the empiric response rate to many medicines, such as antidepressants, is low; this does not obviate their potential clinical and public health value. An overwhelming amount of evidence indicates that MAT can significantly decrease mortality and other undesirable outcomes, a reduction that could be seldom matched by treatments for many other chronic diseases. Nonetheless, diversion of MAT remains a concern, and underscores the importance of greater, rather than fewer, investments in the treatment system to enhance the comprehensiveness and continuity of individuals seeking care for addiction.^{aa}

230. The problem isn't prescription opioids, it is other drugs (e.g., cocaine, alcohol, methamphetamines).^{bb} The increasing presence of fentanyl within the non-opioid supply chain, as well as sharp increases in overdose deaths from stimulants such as cocaine and methamphetamine during the past few years, are the source of increasing concern on the part of clinicians, policy-makers, public health officials and the general public. It is true that many people who overdose from opioids have other drugs in their system at the time of death, that other substance use disorders are common among those with OUD, and that there are shortcomings in our clinical and public health infrastructure to address non-opioid substance use disorders. While these sources of morbidity and mortality require a different public health response than one geared towards opioids alone, they do not diminish the importance of the efforts discussed herein addressing the historic oversupply of opioids and well delineated harms that have resulted from such.
231. Cost-benefit of specific approaches is not clear. The Proposed Abatement Plan discussed herein reflects evidence-based and evidence-informed approaches to address the epidemic in the Communities. Many approaches,^{646,647,648,649} but not all,⁶⁵⁰ have been subject to cost-benefit analysis in a variety of contexts. In some cases, the cost-benefit or cost-effectiveness of proposed abatement measures has been assessed specifically in the context of a single state, such as assessments of adolescent screening interventions performed by the Washington State Institute for Public Policy.⁶⁵¹ Nevertheless, as I note elsewhere, there is a remarkable degree of consensus regarding what abatement strategies are needed, reflecting an acknowledgement of the urgency of the epidemic both nationally and in the Communities, the large body of scientific information underpinning abatement remedies and an awareness of the enormous costs of inaction.
232. It is unclear what success looks like. Some might argue that the success of abatement remedies is ill defined, and that without such clear benchmarks, there is no way to discern whether or not specific remedies are working, or worth it. Fortunately, there is clear consensus regarding how to abate the opioid epidemic, and this is because of the enormous body of scientific evidence underlying it. Plans must be tailored to the Communities, and measurement of process and outcomes is important so as to gauge success. We are now two decades or more into the opioid epidemic, and it may take us just as long to get out of the opioid epidemic as it has to get into it. While there may be different ways of defining success, one measure would be to reduce opioid-related morbidity and mortality by 50% over fifteen years (Paragraph #225), although an even more ambitious measure would be to restore pre-epidemic levels of opioid supply and rates of addiction and overdose deaths.

^{aa} The use of directly observed therapy (DOT) to deliver methadone, and provider administered buprenorphine formulations, are both additional means of reducing potential MAT diversion.

^{bb} Yet an additional objection, that the primary problem is one of heroin and illicit fentanyl, not prescription opioids, is addressed throughout my report and in the Expert Report of Dr. Anna Lembke

IX. CONCLUSIONS

233. The opioid epidemic is the worst drug epidemic in our nation's history, and it has been driven by large increases in the oversupply of prescription opioids for the treatment of pain. The Communities have experienced first-hand morbidity and mortality attributable to the epidemic far greater than most areas of the country, whether with respect to rates of OUD, non-fatal and fatal overdose, and infants born with neonatal abstinence syndrome. These challenges make the substantial investments that the Communities have made to address the local epidemic all the more laudable. Fortunately, while all measures of the epidemic, from prescription opioid sales to rates of addiction to overdose deaths, remain at alarming levels, there is increasing recognition of the magnitude of the harms that have accrued, and remarkable scientific and public health consensus regarding what needs to be done to abate the epidemic. The abatement remedies described herein represent evidence-based and evidence-informed approaches that many communities have already begun to undertake with varying degrees of coordination and scale, and which can be further applied to the Communities, too. They are highly aligned with the three principles highlighted at the outset of this report (Part VI): (1) informing action with evidence; (2) intervening comprehensively; and (3) improving the care of those with pain. As the citizens and leaders of Lake County and Trumbull County know all too well, there is not a moment to lose.

April 16, 2021

A handwritten signature in cursive script that reads "George Caleb Alexander".

G. Caleb Alexander, MD, MS

Baltimore, MD

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Expert Witness Report of G. Caleb Alexander, MD, MS

Appendix A – Johns Hopkins Report: “From Evidence to Impact”



THE OPIOID EPIDEMIC

From Evidence to Impact



JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

THE OPIOID EPIDEMIC

From Evidence to Impact

October 2017

Prepared by

Johns Hopkins

Bloomberg School of Public Health,
and the Clinton Foundation,
Clinton Health Matters Initiative



JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH



The growing crisis of the U.S. opioid epidemic affects all of us, not just those caught in its grip. It is destroying lives, ripping families apart, weakening our communities, and preventing our country from taking full advantage of our greatest resource—our people. We ignore the problem at our peril. We can't afford to lose a single person.

There is no single solution to this grave public health threat, but we know where to start. First we must acknowledge that opioid addiction is a disease that requires comprehensive treatment. Closing the path to addiction means addressing the overprescription of legal opioids and the proliferation of illegal opioids such as heroin and drugs laced with fentanyl. We also have to build the public health response so that families, first responders, and community groups have the support necessary to turn the tide on the epidemic, and in the meantime don't have to bear an impossible economic and emotional burden.

This report contains specific, proven recommendations for how to most effectively combat the epidemic—from allowing physicians to more effectively treat those suffering from addiction; to expanding coverage and accessibility of opioid overdose reversal drugs like naloxone; to changing the way that health care professionals, employers, and advocates talk about addiction to reduce stigma. These recommendations are a critical map for everyone working to fight the opioid crisis in America.

We all have a part to play. At the Clinton Foundation, we have worked since 2012 to help prevent overdose deaths, increase awareness and understanding of the scale of the problem, and frame this as a public health issue. Moving forward, it's up to all of us—leaders from the advocacy, nonprofit, government, and business sectors—to act together. By prioritizing this issue and advancing these recommendations, we can prevent more lives from being lost to this epidemic and ensure a brighter future for all Americans.

A handwritten signature in cursive script, reading "Bill Clinton".

President Bill Clinton, Founder and Chairman of the Board, Clinton Foundation

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Executive Summary

EXECUTIVE SUMMARY

While prescription opioids serve an invaluable role for the treatment of cancer pain and pain at the end of life, their overuse for acute and chronic non-cancer pain as well as the increasing availability of heroin and illicit fentanyl, have contributed to the highest rates of overdose and opioid addiction in U.S. history. Evidence-informed solutions are urgently needed to address these issues and to promote high-quality care for those with pain. This report is a response to that need. By providing an updated and expanded revision of a prior monograph, released in 2015, this report offers timely information and a path forward for all who are committed to addressing injuries and deaths associated with opioids in the United States.

The Opioid Epidemic: From Evidence to Impact reflects a commitment to the three principles that motivated the original report:

- Informing Action with Evidence;
- Intervening Comprehensively; and
- Promoting Appropriate and Safe Use of Prescription Opioids.

Those principles led to the delineation of 10 topic areas across the spectrum of the problem ranging from how clinicians treat pain to treatment for opioid-use disorders to harm reduction strategies.

The findings of the report are comprised of evidence from these 10 topic areas, as well as 49 recommendations that are informed by that evidence.

The first half of the report, Improving the Safe Use of Prescription Opioids addresses five topics:

1. Optimizing Prescription Drug Monitoring Programs
2. Standardizing Clinical Guidelines
3. Engaging Pharmacy Benefits Managers and Pharmacies
4. Implementing Innovative Engineering Strategies
5. Engaging Patients and the General Public

The second half of the report includes five additional topics and is focused on addressing the challenges of Identifying and Treating People with Opioid-Use Disorders:

6. Improving Surveillance
7. Treating Opioid-Use Disorders
8. Improving Naloxone Access and Use
9. Expanding Harm Reduction Strategies
10. Combating Stigma

This report is intended as a resource for policymakers; clinicians who prescribe opioids and those who treat people with opioid-use disorders; people with opioid-use disorders and their families; researchers; journalists; law enforcement officials; health system administrators; employers; service providers and agencies at the local, state, and federal levels; community organizations; and members of the general public. It provides guidance for those who are searching for solutions to address the unacceptable toll of opioid-use disorders in the United States as well as ways to reduce prescription opioid overuse and to maximize the quality of care for those with pain.

Recommendations for Action

RECOMMENDATIONS

OPTIMIZING PRESCRIPTION DRUG MONITORING PROGRAMS

- 1.1 Mandate prescriber PDMP registration and use.
- 1.2 Proactively use PDMP data for education and enforcement.
- 1.3 Authorize third-party payers to access PDMP data with a plan for appropriate use and proper protections.
- 1.4 Empower law enforcement and licensing boards for health professions to investigate high-risk prescribers and dispensers.
- 1.5 Work with industry and state lawmakers to require improved integration of PDMPs into Electronic Health Records systems.
- 1.6 Engage state health leadership to establish or enhance PDMP access across state lines.

STANDARDIZING CLINICAL GUIDELINES

- 2.1 Work with state medical boards and other stakeholders to enact policies reflecting the Centers for Disease Control and Prevention's (CDC's) Guideline for Prescribing Opioids for Chronic Pain.
- 2.2 Mandate electronic prescribing of opioids.
- 2.3 Standardize metrics for opioid prescriptions.
- 2.4 Improve formulary coverage and reimbursement for non-pharmacologic treatments as well as multidisciplinary and comprehensive pain management models.

ENGAGING PHARMACY BENEFITS MANAGERS AND PHARMACIES

- 3.1 Inform and support evaluation research of PBM and pharmacy interventions to address the opioid epidemic.
- 3.2 Continue the development and enhancement of evidence-based criteria to identify individuals at elevated risk for opioid-use disorders or overdose, and offer additional assistance and care to these patients.
- 3.3 Improve management and oversight of individuals who are prescribed opioids for chronic non-cancer pain.
- 3.4 Support restricted recipient (lock-in) programs among select high-risk patient populations.
- 3.5 Improve monitoring of pharmacies, prescribers, and beneficiaries.

IMPLEMENTING INNOVATIVE ENGINEERING STRATEGIES

- 4.1 Continue to support stakeholder meetings to advance technological solutions.
- 4.2 Sponsor design competitions.
- 4.3 Secure funding for research to assess the effectiveness of innovative packaging and designs available and under development.
- 4.4 Use research to develop implementation strategies in advance of identification of effective products.
- 4.5 Work with industry and government agencies to identify opportunities for the development and rigorous evaluation of abuse-deterrent formulations of prescription opioids.

RECOMMENDATIONS

ENGAGING PATIENTS AND THE GENERAL PUBLIC

- 5.1 Convene a stakeholder meeting with broad representation to create guidance that will help communities undertake comprehensive approaches that address the supply of, and demand for prescription opioids in their locales; implement and evaluate demonstration projects that model these approaches.
- 5.2 Convene an inter-agency task force to assure that current and future national public education campaigns about prescription opioids are informed by the available evidence, and that best practices are shared.
- 5.3 Provide clear and consistent guidance on safe storage of prescription opioids.
- 5.4 Provide clear and consistent guidance on safe disposal of prescription opioids and expand take-back programs.

IMPROVING SURVEILLANCE

- 6.1 Invest in surveillance of opioid misuse and use disorders, including information about supply sources.
- 6.2 Develop and invest in real-time surveillance of fatal and non-fatal opioid overdose events.
- 6.3 Use federal funding for interventions to address opioid-use disorders to incentivize inclusion of outcome data in those funded programs.
- 6.4 Support the linkage of public health, health care, and criminal justice data related to the opioid epidemic.

TREATING OPIOID-USE DISORDERS

- 7.1 Provide a waiver from patient caps for buprenorphine treatment for clinics that implement evidence-based models of care.
- 7.2 Require all state-licensed addiction treatment programs that admit patients with opioid-use disorders to permit access to buprenorphine or methadone.
- 7.3 Require all Federally Qualified Health Centers to offer buprenorphine.
- 7.4 Allocate federal funding to build treatment capacity in communities with high rates of opioid addiction and limited access to treatment.
- 7.5 Develop and disseminate a public education campaign about the role of treatment in addressing opioid addiction.
- 7.6 Educate prescribers and pharmacists how to prevent, identify, and treat opioid addiction.
- 7.7 Establish access to opioid agonist treatment with buprenorphine and methadone maintenance in jails and prisons.
- 7.8 Incentivize initiation of buprenorphine in the emergency department and during hospital stays.

IMPROVING NALOXONE ACCESS AND USE

- 8.1 Partner with product developers to design naloxone formulations that are easier to use by non-medical personnel and less costly to deliver.
- 8.2 Work with insurers and other third-party payers to ensure coverage of naloxone products.
- 8.3 Work with community-based overdose education and naloxone distribution programs to identify stable funding sources to ensure program sustainability.
- 8.4 Engage with the scientific community to assess the research needs related to naloxone distribution evaluations and identify high priority future directions for naloxone-related research.

RECOMMENDATIONS

8.5 Engage with the health care professional community to advance consensus guidelines on the co-prescription of naloxone.

8.6 Assess the effects of state laws expanding naloxone access to the general public.

EXPANDING HARM REDUCTION STRATEGIES

9.1 Establish and evaluate supervised consumption spaces.

9.2 Work with state and local stakeholders to establish and support needle and syringe service programs.

9.3 Evaluate and disseminate the use of test kits for fentanyl-laced opioids.

COMBATING STIGMA

10.1 Update employer human resources and benefits language to avoid stigmatizing language and include evidence about the effectiveness of treatment for opioid-use disorders.

10.2 Avoid stigmatizing language and include information about the effectiveness of treatment and the structural barriers that exist to treatment when communicating with the public about opioid-use disorders.

10.3 Educate health care providers about the benefits associated with destigmatizing language.

TOP TEN RECOMMENDATIONS FOR ACTION

1.1 Mandate prescriber PDMP registration and use.

2.1 Work with state medical boards to enact policies reflecting the Centers for Disease Control and Prevention's (CDC's) Guideline for Prescribing Opioids for Chronic Pain.

3.1 Inform and support evaluation research of PBM and pharmacy interventions to address the opioid epidemic.

4.3 Secure funding for research to assess the effectiveness of innovative packaging and designs available and under development.

5.4 Provide clear and consistent guidance on safe disposal of prescription opioids; expand take-back programs.

6.1 Invest in surveillance of opioid misuse and use disorders, including information about supply sources.

7.4 Allocate federal funding to build treatment capacity in communities with high rates of opioid addiction and limited access to treatment.

8.1 Partner with product developers to design naloxone formulations that are easier to use by non-medical personnel and less costly to deliver.

9.1 Establish and evaluate supervised consumption spaces.

10.2 Avoid stigmatizing language and include information about the effectiveness of treatment and the structural barriers that exist to treatment when communicating with the public about opioid-use disorders.

From the Editors

FROM THE EDITORS

Prescription opioids serve an invaluable role for the treatment of cancer pain and pain at the end of life. Despite this, their overuse, especially for chronic non-cancer pain, remains a major public health challenge in the United States. Overdoses from heroin and illicit fentanyl have also come into sharp focus, with large increases in fatal overdoses from these drugs since 2010. In 2016, about 64,000 people died from drug overdoses in the United States,¹ and both experts² and projected data^{3,4} suggest that deaths from opioids will increase further still in the years to come⁵.

The opioid epidemic has manifested in many ways, and early reports of rising overdoses have been followed by many other signs of the serious effects that the epidemic has had on society's health and productivity. Rates of neonatal abstinence syndrome have increased 400 percent from 2000 to 2012. Where these cases reflect unstable home environments, children face significant social risks.⁶ In some parts of the country, the epidemic has further strained an already vulnerable foster care system, with nearly half a million children in the system in 2015.⁷ High rates of intravenous drug use among individuals with opioid-use disorders have led to local outbreaks of HIV and Hepatitis C.^{8,9} The epidemic is so far-reaching that it is an important factor contributing to the declining life expectancy of the nation.¹⁰

Alongside these consequences is the fact that millions of Americans continue to experience high levels of chronic pain.¹¹ Such pain is a major source of disability and in addition to being associated with conditions such as depression and anxiety, chronic pain is also associated with increased mortality from other causes such as cardiovascular disease.¹² While several factors have contributed to the large increases in prescription opioid use in the past two decades, the high prevalence of chronic pain has been an important driver.

In 2014, at the invitation of the Clinton Foundation and the Johns Hopkins Bloomberg School of Public Health, a diverse group of experts came together to chart a path forward to address the opioid epidemic. The group, including clinicians, researchers, government officials, injury prevention professionals, law enforcement leaders, pharmaceutical manufacturers and distributors, lawyers, health insurers, and patient representatives, reviewed the current state of the evidence, identified strategies to address alarming trends in injuries and deaths from these drugs, and made recommendations for action that were released in 2015.¹³ More than two years later, despite the efforts of many committed stakeholders, far too many lives continue to be lost.

While more injuries and deaths are occurring from opioids than ever before, the epidemic has also evolved. The volume of opioids prescribed, while still dwarfing that of other countries, plateaued in 2010 and since then, prescribing volume has modestly declined. In many communities, there is increasing awareness of the epidemic as well as a growing demand for prevention and treatment services. Increasing public support for such treatment has led to bipartisan efforts to improve funding and the delivery of more comprehensive and coordinated care for those with opioid-use disorders. Health care organizations, ranging from professional societies to health systems to pharmacies, are modifying their policies, procedures, and best practices to improve the care of those in pain and to identify and treat those with opioid-use disorders.

In this context, we have taken a fresh look at what remains a daunting challenge – stemming the tide of opioid-related injuries and deaths in the United States and improving care for those in pain. In addition to updating the evidence-base and timeliness of prior recommendations, we have also made several other modifications to our report, such as addressing the role of stigma and harm reduction in improving the treatment system. Our report reflects many changes from our previous analysis, but our commitment to the principles which motivated it remain unchanged:

INFORMING ACTION WITH EVIDENCE

An increasing number of evidence-based interventions exist to inform action to address this public health emergency; these should be scaled up and widely disseminated. Furthermore, many promising ideas remain evidence-informed, but have not yet been rigorously evaluated. The urgent need for action requires that we continue to rapidly implement and carefully evaluate these promising policies and programs. The search for new, innovative solutions also needs to be supported.

INTERVENING COMPREHENSIVELY

We support approaches that intervene all along the supply chain, and in the clinic, community, and addiction treatment settings. Interventions aimed at stopping individuals from progressing down a pathway that will lead to misuse, addiction, and overdose are needed. Effective primary, secondary, and tertiary prevention strategies are vital, including among those actively using opioids non-medically. The importance of creating synergies across different interventions to maximize available resources is also critical.

FROM THE EDITORS

PROMOTING APPROPRIATE AND SAFE USE OF PRESCRIPTION OPIOIDS

Used appropriately, prescription opioids can provide relief to patients. However, these therapies are often prescribed in quantities and for conditions that are excessive, and in far too many cases, beyond the evidence base. Such practices, and the lack of attention to safe use, storage, and disposal of these drugs, contribute to opioid-use disorders and the overdose increases that have occurred. We support efforts to maximize the favorable risk-benefit balance of prescription opioids by optimizing their use in circumstances supported by evidence-based clinical practice guidelines.

In summary, this report provides a comprehensive, updated review of these target points of opportunity and summarizes the evidence in support of these recommendations for advancing the field through policy and practice. With rapid increases in the prevalence of opioid-use disorders and overdose deaths in this country as well as high rates of untreated pain, we are committed to assuring that what is known through research is translated to policymakers and practitioners. Uptake and implementation of these recommendations are needed to address the opioid epidemic that continues to devastate families and communities throughout our country. Thank you for your personal efforts to help turn the tide.

G. Caleb Alexander, M.D., M.S.
Shannon Frattaroli, Ph.D., M.P.H.
Andrea Gielen, Sc.D., Sc.M.

Improving the Safe Use of Prescription Opioids

IMPROVING THE SAFE USE OF PRESCRIPTION OPIOIDS

Prescription opioids serve a vital role in the treatment of cancer pain and pain at the end of life. However, during the past two decades, their use in many other clinical settings, especially for the treatment of chronic non-cancer pain, has soared. Between 1999 and 2012, the volume of opioids prescribed increased more than 400 percent, such that by 2012, enough opioids were dispensed to provide every adult in the United States with a one-month continuous round-the-clock supply of pills.

These increases in use have been accompanied by consistent increases in rates of addiction, injuries, and overdose deaths, such that drug overdoses are now the leading cause of death among Americans under 50 years of age.¹⁴ Since 2010, modest declines in opioid sales have been reported, though the United States remains a far outlier when it comes to opioid prescribing, and there is also enormous variation in rates of opioid use around the country. In addition, concerns regarding injuries and deaths from prescription opioids have been accompanied by a growing awareness of rapid increases in overdoses from heroin and illicit fentanyl.

The vast majority of prescription opioids that are misused come from medications that are prescribed, dispensed, and then used for non-medical purposes,^{15, 16} both by patients who receive the prescriptions as well as friends and family members. Physicians and other health care providers overprescribe opioids for several reasons, and a small proportion of providers account for the majority of opioids prescribed.^{17, 18} Health care providers who write or refill an opioid prescription provide a simple, discrete response which takes less time than educating a patient or providing counseling on non-pharmacologic therapies for pain management in busy practice settings where patients may expect to receive a prescription.¹⁹ Referrals to multidisciplinary and subspecialty management for pain medicine are not accessible in all regions of the United States. Prescribers have a limited number of non-opioid medicines to treat patients who have moderate to severe chronic pain.²⁰ Pharmaceutical companies promote opioids through opioid related payments to advocacy and professional organizations²¹ as well as directly to prescribers, which 1 in 12 US physicians received between 2013 and 2015.²²

Challenges in the safe storage and proper disposal of prescription opioids also contribute to the opioid crisis. Most patients fail to store opioid products in locked locations, including patients with children and adolescents who are particularly vulnerable to risks of opioid misuse and overdose.^{23, 24} Many patients also retain unused opioids instead of disposing with them using methods such as those suggested by the U.S. Food and Drug Administration (FDA).²⁵ Collectively, these practices create household reservoirs of opioids that facilitate misuse and diversion all across America. In some cases, prescription opioids are diverted intentionally, while in other cases, they are used without the knowledge of the person for whom they were prescribed. Approximately 70 percent of people who report non-medical use of prescription opioids state their most recently used drug came from a friend or family member.²⁶

The non-medical use of prescription opioids impacts communities across the nation and remains a major challenge, despite modest reductions in opioid sales²⁷ and non-medical use²⁸ during the past few years. It is a problem that involves a legal product that is manufactured, marketed and dispensed by professionals through a system that is subject at multiple points to government oversight from different agencies at the federal and state level. That system has been ineffective in preventing the oversupply of prescription opioids to communities where demand for these products has grown. The supply of prescription opioids is connected to the manufacturing sector that controls production (e.g., the amount of product produced), chemistry (e.g., strength, composition, properties) and characteristics (e.g., crush resistance of pills, shelf life) of the drugs produced.

In the sections that follow, we consider five areas of effective response:

1. **Prescription Drug Monitoring Programs**, state-level programs governing the use of controlled substance prescribing information for providers, law enforcement and other stakeholders;
2. **Clinical Guidelines** that synthesize information regarding the safety, effectiveness and risk-benefit balance of prescription opioids in different clinical settings;
3. **Pharmacy Benefits Managers and Pharmacies**, two important stakeholders in the supply chain whose policies and procedures can reduce unsafe opioid use;
4. **Engineering Strategies**, such as innovative packaging solutions that can reduce non-medical opioid use as well as diversion;
5. **Patient and Public Engagement**, such as coordinated, community-based initiatives to raise awareness and facilitate action alongside other interventions that address the larger context in which the epidemic is occurring.

1. OPTIMIZING PRESCRIPTION DRUG MONITORING PROGRAMS

Prescription Drug Monitoring Programs (PDMPs) collect information about controlled substance prescriptions from in-state pharmacies and, for most PDMPs, mail order pharmacies that ship prescriptions into a state. Every state, as well as the District of Columbia and Territory of Guam, has a PDMP.²⁹ Through online access to their state's database, physicians and other prescribers can obtain clinical information regarding patients' controlled substance prescriptions to inform treatment decisions. Typically, information available through the PDMP includes drug name, type, strength, and quantity of drugs from previous prescriptions. Pharmacists can access PDMP data prior to dispensing a controlled substance prescription. PDMPs organize patient data in one location about controlled substance use in a way that can promote a culture of patient safety and quality of care.

One state-level survey revealed that 70 percent of physicians believed that the PDMP reduced the volume of opioids that they prescribed while increasing their comfort level with such prescribing; three-fourths of respondents (74%) reported that the data provided by the PDMP were very useful for informing opioid prescribing.³⁰ There is also evidence that PDMP implementation is associated with significant decreases in opioid prescriptions and opioid-related morbidity and mortality,^{31, 32, 33} although the literature also includes findings suggesting otherwise,³⁴ and the effects of laws mandating PDMP registration and use remain an important area for further study.

PDMPs are under-used by prescribers. More than a quarter (28%) of primary care physicians in one national survey reported not being aware of their state's PDMP. While most clinicians (53%) reported having obtained data from their PDMP at some point, they accessed data in fewer than a quarter of the instances when they prescribed an opioid.³⁵ Physicians identify a number of barriers to PDMP use, including that retrieving the information is too time consuming in the context of busy clinical practice and that it is not user-friendly.³⁶

While prescriber PDMP use may mitigate risks of opioid prescribing, practitioners may continue to unknowingly prescribe opioids to persons who will develop or already have opioid-use disorders. Such individuals are also at potential risk of heroin use as well as exposure to illicit fentanyl.³⁷ With the benefit of PDMP use, prescribers who identify persons with opioid-use disorders should refer them to appropriate treatment centers and addiction specialists.

To reduce illicit prescription opioid trafficking, law enforcement access to PDMP data is critical. Criminal enterprises such as "pill mills" that issue prescriptions for cash with no clinical evaluation, organized forgery, or doctor shopping rings facilitate non-medical prescription opioid use, and these supply channels should be a priority for law enforcement intervention.⁵⁷ Despite this, careful regulation of when and how law enforcement investigators access and use PDMP data is important. Concerns that unfettered access could lead to individuals with opioid dependence being subject to criminal prosecution as opposed to being directed to treatment must be considered.^{38, 39, 40}

If PDMP registration can serve as a proxy for awareness, prescriber use remains a challenge, as even the highest rates of PDMP registration do not ensure use. For example, during the first quarter of 2012, Kentucky had the fifth highest proportion of registered prescribers of any state (49%), yet prescribers and pharmacists requested information for only six percent of the 2.9 million controlled substance prescriptions dispensed.⁴¹ As of September 2017, 30 states mandated prescriber PDMP enrollment, and 28 required pharmacist enrollment.^{42, 43, 44}

In response to the problem of low PDMP use, state lawmakers and PDMP administrators have made several adjustments, including:

- Authorization of delegates, such as approved prescribers' staff, to request PDMP data. As of September 2017, 48 states and the District of Columbia had laws authorizing delegates to request PDMP data, though only 36 had engaged in such reporting.⁴⁵
- Establishment of interoperability with electronic health records and health information exchanges developed through the Affordable Care Act. The Substance Abuse and Mental Health Services Administration (SAMHSA) is providing grants to support this work in 16 states.⁴⁶ As of September 2017, PDMPs in 27 states offer health information exchange integration.⁴⁷
- Proactive analysis of PDMP data and forwarding of unsolicited reports to prescribers and pharmacists noting when individuals' prescribing patterns are outliers. When prescribers receive unsolicited reports from PDMP administrators, they increase their own data requests, suggesting an increased vigilance with regard to prescribing decisions.^{48, 49}

OPTIMIZING PRESCRIPTION DRUG MONITORING PROGRAMS

- Increased speed of data collection. Oklahoma collects data at the point of sale; another 42 states and the District of Columbia collect data daily, and eight states collect data every 3-8 days.^{37, 50}
- Increased interstate PDMP data sharing so prescribers can observe prescriptions dispensed in other states. Forty-three states share data with other states and six others are working toward these agreements.⁵¹

States with low prescriber utilization are also increasingly mandating PDMP use. As of September 2017, 39 states mandate PDMP use under some circumstances.³⁷ Kentucky, in 2015, was the first state to mandate comprehensive PDMP use. Prescribers' PDMP use increased following the mandate,⁵² and decreases in opioid prescribing, doctor shopping, and prescription overdose hospitalizations were noted in a 2015 evaluation. Although heroin treatment admissions rose during the study period, this increase began prior to the mandate. Like Kentucky, other comprehensive mandate states, such as Tennessee, New York, Ohio, and Wisconsin, experienced rapid increases in PDMP registrations, PDMP use, and prescribing of buprenorphine, indicative of increased treatment of opioid-use disorders.^{53, 54} States also experienced decreases in high-risk prescribing, including for commonly misused controlled substances; combination prescribing of opioids, benzodiazepines, and muscle relaxants; and in multiple provider, or "doctor-shopping," episodes. As of September 2017, 24 states have enacted statutory mandates for comprehensive PDMP use and such mandates have been recommended by the National Governors Association,⁵⁵ Pew Charitable Trusts,⁵⁶ and Shatterproof, an organization representing families.⁵⁷ While specific criteria for use vary, in some settings use is mandated when opioids are prescribed for the first time, and if treatment continues, every 90 days thereafter, except for specific circumstances such as for prescriptions of three days or less without refills or for terminally ill patients.

Additional professional groups that could use PDMP data to reduce opioid overuse and diversion include:

Third-party health care payers and their pharmacy benefit managers (PBMs) that can intervene with prescribers, dispensers, and patients.^{58,59}

Professional licensing boards that oversee clinicians and have an interest in identifying who may be self-prescribing for a possible opioid-use disorders as well as who has high-risk prescribing or dispensing patterns.^{60,61,62}

Public health agencies that provide an early warning system for communities about the risks of opioid overdose and death^{63,64} and intervene to prevent further harms.^{65,66} This should include identifying persons at high risk due to co-prescribing of opioids and benzodiazepines, high volume morphine milligram equivalents, and other factors. Public health interventions should be employed as when disease registries identify persons who have positive infectious disease laboratory reports. Public health authorities can also take administrative action, such as revoking a state authorization to prescribe controlled substances, for prescribers who are practicing medicine far outside the standard of care.

RECOMMENDATIONS FOR ACTION

1.1 MANDATE PRESCRIBER PDMP REGISTRATION AND USE

States should mandate prescriber PDMP registration and use in order to achieve more comprehensive and effective use of PDMP data in treating patients. Access to this information should be a routine part of patient care as new ways are sought to maximize the value of PDMP information to clinicians and patients. Criteria guiding requirements for mandated use have been established. Such changes will require modifications to clinical workflow that in turn will require additional resources to address.

Rationale: Mandatory PDMP registration and use policies are associated with increased use, and most evidence suggests PDMP use is associated with decreased opioid prescribing and adverse events.

Current Status: Thirty states mandate PDMP registration and 39 mandate that prescribers register and use PDMPs in at least some clinical circumstances.

OPTIMIZING PRESCRIPTION DRUG MONITORING PROGRAMS

1.2 PROACTIVELY USE PDMP DATA FOR EDUCATION AND ENFORCEMENT.

States should analyze their PDMP data to identify:

1. High volume prescribers who deviate from standards of care for review;
2. Potential inappropriate or illegal activities for increased oversight of controlled substance prescribing; and
3. Inappropriate and/or illegal use for intervention. Primary recipients of PDMP data reports should include prescribers, dispensers, professional licensing boards, law enforcement agencies, and state and community prevention and treatment programs.

The types of information included in data reports should vary depending on recipients' roles. For example, reports to law enforcement should focus on identifying clinics or providers with exceptionally high volume prescribing that may signal illegal activities.

Rationale: Many PDMPs underutilize their data and do not engage in proactive reporting, nor do they participate in the Prescription Behavior Surveillance System or state-based equivalent reporting. Better use of PDMP data will help to identify opportunities for intervention and prevent non-medical use and overdose through education and enforcement.

Current Status: Forty states engage in proactive data analysis and reporting as of September 2017. Only five states provide unsolicited reports to all four primary recipient groups: prescribers, dispensers, professional licensing boards, and law enforcement agencies.⁶⁸

Twelve states participate in the Prescription Behavior Surveillance System by sending de-identified PDMP data to and receiving reports from the Brandeis PDMP Center of Excellence. The Centers for Disease Control and Prevention and the Food and Drug Administration fund the project through an agreement with the Bureau of Justice Assistance.⁶⁹ States not participating in the Prescription Behavior Surveillance System can initiate their own data analysis and sharing with state and community prevention and treatment programs.

1.3 AUTHORIZE THIRD-PARTY PAYERS TO ACCESS PDMP DATA WITH A PLAN FOR APPROPRIATE USE AND PROPER PROTECTIONS

States should authorize Medicaid, Medicare, the Veterans Administration, Department of Defense, Indian Health Service, workers' compensation carriers, and private third-party health care payers to access PDMP data for their enrollees. This access should come with patient protections to assure, for example, that data sharing does not result in changes in coverage or pricing.⁷⁰ The authorization should also allow Pharmacy Benefit Managers to access the data as agents of the third-party payers for whom they manage benefits. See Section 3 of this report for more information on Pharmacy Benefit Managers.

Rationale: Access to PDMP data can provide third-party payers with the ability to identify and contact prescribers whose prescribing practices expose enrollees to unnecessary risks; identify enrollees who are obtaining high-risk prescriptions, contact their prescribers, create prescription limitations, and monitor compliance thereafter; and identify pharmacies where dispensing may put enrollees at risk. Such access may provide valuable information to inform internal policies that address opioid-use disorders associated with prescribed opioids. Careful consideration of enrollee protections is essential to protecting patients' rights and guarding against abuse.

Current Status: Thirty-six states and one territory authorize some combination of third-party payers to access PDMP data. Seven states provide access to Medicare and five states to commercial third-party payers.⁷¹ Washington State authorizes Medicaid and Workers Compensation to access the PDMP data in bulk.⁷²

OPTIMIZING PRESCRIPTION DRUG MONITORING PROGRAMS

1.4 EMPOWER LAW ENFORCEMENT AND LICENSING BOARDS FOR HEALTH PROFESSIONS TO INVESTIGATE HIGH-RISK PRESCRIBERS AND DISPENSERS

States should direct their PDMPs to proactively analyze these data to promote best standards of patient care and safety associated with opioid prescribing. Where such analyses reveal possible misconduct, that information should be provided to licensing boards and law enforcement for review.

Rationale: The centralized information source provided by PDMPs offers an opportunity for states to promote these data as tools for improving quality of care and patient safety. When questions about possible misconduct arise, licensing boards need access to PDMP data to review possible misconduct, and when warranted, share that information with the relevant law enforcement authorities.

Current Status: Forty-five states, Guam, and the District of Columbia permit their licensing boards to access PDMP data; 18 of the states send unsolicited reports to licensing boards.⁷³

Twenty states proactively analyze and send unsolicited reports to law enforcement agencies, and 28 allow law enforcement to solicit reports.⁷⁴

1.5 WORK WITH INDUSTRY AND STATE LAWMAKERS TO REQUIRE IMPROVED INTEGRATION OF PDMPs INTO ELECTRONIC HEALTH RECORDS SYSTEMS

Most PDMPs are largely web-based, standalone platforms requiring a separate workflow. This is inefficient and substantially decreases their utility and promise.

Rationale: PDMP use takes up to three times longer than other computer-based tasks, and the additional time and effort required is a large barrier to regular use.^{75,76} Incorporating PDMPs into Electronic Health Records systems has the potential to reduce this burden and increase use.⁶⁷

Current Status: The Office of the National Coordinator for Health Information Technology, in coordination with SAMHSA and others, has been involved in trials to integrate PDMPs into Electronic Health Records systems in a variety of settings, with generally positive results.⁷⁷ Twenty-seven states offer one or more forms of PDMP integration with Electronic Health Records and/or health information exchanges.⁷⁸

1.6 ENGAGE STATE HEALTH LEADERSHIP TO ESTABLISH OR ENHANCE PDMP ACCESS ACROSS STATE LINES

Enact state policies that mandate interconnection of state PDMPs.

Rationale: In many areas of the U.S. PDMPs are of limited effectiveness if providers are unable to access information about prescriptions in neighboring states.⁷⁹

Current Status: Forty-three states currently engage in interstate PDMP interoperability and six are working toward it as of 2017.⁸⁰

2. STANDARDIZING CLINICAL GUIDELINES

A balanced approach to the opioid epidemic acknowledges both that appropriate and evidenced-based opioid prescribing benefits some groups of patients, and that urgent action is needed to minimize harm from the use of these products in many settings where they have an unfavorable risk-benefit balance.^{81,82} Data-driven analyses and the clinical community broadly support opioids as part of a multimodal regimen in the treatment of acute pain after surgery,⁸³ cancer pain,^{84,85} and pain in end-of-life, hospice, and palliative settings.⁸⁶ While indicated, opioid prescribing in some acute clinical contexts may contribute to harms by inadvertently transitioning patients from short-term to long-term use and facilitate the development of opioid-use disorders in some patient subgroups.^{87,88} At the same time, policies to support appropriate access to prescription opioids may be associated with fewer unintended consequences than overly broad and blunt restrictions on opioid prescribing.⁸⁹

Prescription opioids have been demonstrated as efficacious for the short-term treatment of chronic non-cancer pain, such as that caused by headaches, fibromyalgia, or lower back pain. For example, opioids have been shown to reduce nociceptive and neuropathic pain in chronic non-cancer settings for durations less than 16 weeks.^{90,91} However, there is little to no moderate or high-quality evidence suggesting the long-term benefits from prescription opioids among patients with these diagnoses. In addition, data clearly shows that long-term opioid use increases the risk of adverse outcomes such as opioid misuse, overdose, and other adverse events.⁹² Widely accepted clinical guidelines for chronic non-cancer pain do not recommend prescription opioids as first-line treatment.^{93,94} Rather, these guidelines recommend non-pharmacologic and non-opioid pharmacologic therapies as the preferred treatment for chronic pain, a careful assessment of risks and benefits when considering opioid prescribing, and only prescribing opioids when benefits are anticipated to outweigh risks. Despite this, several factors, including a lack of studies assessing long-term outcomes of opioid therapy for chronic pain and misperceptions on the part of prescribers and patients regarding the appropriateness of opioids for chronic pain, persist. The net result is that many clinicians continue to prescribe opioids for patients with chronic non-cancer pain in a manner at odds with the best available evidence.

In 2016, the Centers for Disease Control and Prevention (CDC) published a Guideline for Prescribing Opioids for Chronic Pain. The Guideline provides the most recent and comprehensive synthesis of data on opioid prescribing for chronic non-cancer pain.⁹⁵ The CDC's guidelines carefully balance the risks and benefits of opioid prescribing. The synthesis of evidence details when to start or continue opioids, how to select opioids and conduct patient follow-up, and how to assess the benefits and risks from prescription opioids in patients with chronic non-cancer pain. Because the dose of opioid medication differs based on the type of opioid prescribed, prescribers need to calculate morphine milligram equivalents (MME) to understand the risks associated with opioid prescribing. A continuum of risks exists as MME increases, and no established MME dose fully mitigates the risk of opioid use. Despite this, recommended thresholds that

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN United States, 2016

The CDC Guideline addresses patient-centered clinical practices including conducting thorough assessments, considering all possible treatments, closely monitoring risks, and safely discontinuing opioids. The three main focus areas in the Guideline include:

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

- Evaluation of risk factors for opioid-related harms and ways to mitigate patient risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid-use disorders

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. *MMWR Recomm Rep* 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

STANDARDIZING CLINICAL GUIDELINES

denote increased risk include doses of 50 MME/day, 90-100 MME/day, and 200 MME/day.

While much of the focus of the opioid epidemic has been on prescription opioids, there are many alternative pharmacologic and non-pharmacologic treatments that can be used to manage chronic non-cancer pain. Additional non-opioid pharmacologic agents include acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), select anti-depressants, muscle relaxants, select anticonvulsants, and topical analgesics. The appropriateness of these non-opioid treatments depends upon a variety of factors, including the origin and type of pain, patient age and comorbidities, and patient and clinician experience and preference, to name a few. There are also many non-pharmacologic therapies that can be used for the management of pain, including physical therapy, therapeutic massage, acupuncture, biofeedback, yoga, and heat or cold therapies. Efforts to improve care for those in pain as well as to reduce the overuse of prescription opioids, should be informed by knowledge and examination of these complements and alternatives to opioids,⁹⁶ and in some cases, the adequacy of insurance coverage supporting their use.⁹⁷

There is also growing interest in the potential role of cannabis in the management of those with chronic non-cancer pain. Chronic pain is the most common indication for medical cannabis, and there is some suggestive evidence from ecological studies indicating that opioid use⁹⁸ and overdose are reduced after states implement medical cannabis laws.^{99,100} However, there is a dearth of high-quality evidence from controlled trials on the effectiveness of cannabis as a supplement for opioids, and there is also evidence that cannabis use may increase risk of non-medical prescription opioid use and prescription opioid-use disorders.¹⁰¹ In 2017, the National Academies of Sciences, Engineering, and Medicine noted that cannabis can effectively treat chronic pain, but also underscored that there is uncertainty and known adverse outcomes associated with cannabis use, such as the risk of motor vehicle accidents.¹⁰² Most studies demonstrated short-term reductions in pain using oral cannabis extracts, such as nabiximol, in trials outside of the U.S., while a small group of U.S.-based studies suggested that a vaporized or smoked cannabis flower reduces chronic pain in the short-term. However, cannabis available for medical research differs in formulation, strength, and chemical composition from cannabis products sold to consumers in state markets. Consequently, the safety and efficacy of commercially available cannabis products is largely unknown.

Providers may prescribe opioids through a written or electronic prescription. Electronic prescribing of prescription opioids offers numerous advantages, including fewer dosing errors, reduced fraud, greater security through two-factor authentication, and enabling enhanced surveillance.¹⁰³ Electronic prescribing also facilitates the use of clinical decision support tools that can guide prescribers to implement evidenced-based practices during routine clinical care.¹⁰⁴ While federal regulations in the U.S. Drug Enforcement Agency's Practitioner's Manual only permit written prescriptions for opioids, the Agency permitted electronic prescribing for controlled substances in 2010 which effectively legalized electronic prescribing of controlled substances in all 50 states. However, only one in five providers work in health systems that enable electronic prescribing and fewer than 15 percent of controlled substance prescriptions are electronic.^{105,106}

RECOMMENDATIONS FOR ACTION

2.1 WORK WITH STATE MEDICAL BOARDS AND OTHER STAKEHOLDERS TO ENACT POLICIES REFLECTING THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S (CDC'S) GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

State medical boards should take concrete steps toward implementing the CDC's Guideline. Such steps might include use of the Guideline during disciplinary investigations as one factor for deciding whether a physician is practicing outside the standard of care. Such an approach will save the time and money involved in developing separate guidelines, and will contribute toward national parity with regard to prescription policies.

Rationale: The Guideline, issued in 2016, remains the gold standard for a comprehensive, evidence-based approach to prescribing opioids for chronic non-cancer pain in primary care. These evidence-based recommendations set the standard for how to address co-prescribed medications, safety information on dosing standards, and guidance from writing the first prescription to tapering patients.

Current Status: Since releasing the Guideline in 2016, the CDC has developed a variety of resources, including a companion smartphone app, to foster dissemination and implementation.¹⁰⁷ While dissemination of the Guideline has resulted in high rates of awareness among providers and policymakers, implementation across states remains an understudied area.

STANDARDIZING CLINICAL GUIDELINES

2.2 MANDATE ELECTRONIC PRESCRIBING OF OPIOIDS

Federal agencies and state jurisdictions should accelerate the adoption of electronic opioid prescribing through mandates to health systems and prescribers.

Rationale: Electronic opioid prescribing offers multiple advantages to written prescriptions, including improving surveillance of opioid prescribing and reducing rates of error, duplication, and forged prescriptions. Electronic prescribing also permits the use of clinical decision support systems, which help providers apply evidenced-based guidelines when prescribing opioids.

Current Status: Electronic prescribing of controlled substances is legal in all 50 states. As of September 2016, only one in five providers have health systems that enable electronic prescribing and fewer than 15 percent of transactions for prescriptions for controlled substances occur electronically.^{108,109}

2.3 STANDARDIZE METRICS FOR OPIOID PRESCRIPTIONS

Federal Drug Enforcement Agency regulations should mandate that opioid prescriptions identify and record daily and total morphine milligram equivalents (MME) as measures of opioid exposure.

Rationale: The effective dose of opioid varies based on the type of opioid prescribed. MMEs require calculation and convey important information about the risk of opioids to prescribers, patients, and payers.

Current Status: The Drug Enforcement Agency has no mandate that opioid prescriptions include total and daily MMEs on opioid prescriptions.

2.4 IMPROVE FORMULARY COVERAGE AND REIMBURSEMENT FOR NON-PHARMACOLOGIC TREATMENTS AS WELL AS MULTIDISCIPLINARY AND COMPREHENSIVE PAIN MANAGEMENT MODELS

Payers should invest in care models for chronic pain that emphasize non-pharmacologic treatments as well as collaborative care by different medical specialties and non-physician caregivers.

Rationale: Evidence-based non-opioid treatments such as cognitive behavioral therapy, physical therapy, exercise, and acupuncture represent tools for the management of chronic pain that may help patients avoid initiation of opioid therapy or transition from long-term opioid use. Formularies drive patients and providers toward preferred treatment choices. Improving coverage of non-opioid alternatives would help to promote the use of pharmacologic and non-pharmacologic approaches that have a better risk-benefit balance than opioids for many patients.

Current Status: Formulary coverage and reimbursement for non-pharmacologic and multidisciplinary pain treatment does not have parity with traditional models of health care that emphasize medication prescribing and encounters with physicians, and even when covered, utilization management criteria such as prior authorization and quantity limits may prevent access to non-pharmacologic treatments.

3. ENGAGING PHARMACY BENEFITS MANAGERS AND PHARMACIES

Pharmacy Benefits Managers (PBMs) manage the pharmacy benefits for health plans and large employers, and thus, have an important opportunity to help reverse the opioid epidemic through coverage policies and programs, policies and procedures to reduce inappropriate prescribing and to intervene with individuals likely to be diverting prescription opioids or using them for non-medical purposes. Because PBMs work closely with health plans to design coverage benefits, some analyses have focused jointly on the role that PBMs and health insurers can play, especially in populations such as Medicaid recipients where non-medical use and opioid-use disorders are more common relative to other insured populations.¹¹⁰

PBMs can use several approaches to improve the safe use of prescription opioids. First, PBMs can use “formulary controls” to guide patients and prescribers toward the safest, most cost-effective medications and cover these drugs at a lower member cost share to encourage their use. The degree to which PBMs have effectively deployed these programs with a priority towards maximizing the safe use of opioids is not clear,¹¹¹ and opportunities undoubtedly remain. Some products, such as extended-release hydrocodone, promethazine with codeine syrup, and carisoprodol,¹¹² have been excluded from some formularies due to concerns about the potential for non-medical use. The ultimate goal of formulary design should be to ensure safe, cost effective therapy and better quality of care, consistent with the CDC’s Guideline for Prescribing Opioids for Chronic Pain.¹¹³

In addition to formulary design, PBMs employ utilization management programs such as concurrent drug utilization review, prior authorization, precertification, and quantity limits to reduce non-medical use and diversion. Reports suggest significant reductions in opioid prescribing from these programs^{114,115,116} though evaluations tend to be proprietary, as well as limited in the type of outcomes examined. Just as utilization management strategies may be deployed to restrict opioid use, removal of such programs may be undertaken to improve access to buprenorphine treatment for opioid dependence.¹¹⁷ For patients who have particularly high-risk controlled substance use and whose utilization cannot be safely addressed using other mechanisms, insurers or PBMs may enroll the member in a pharmacy and/or prescriber restriction program. These programs, also known as “lock-in” programs, are applied to fewer than 1 in 1,000 individuals who are prescribed controlled substances, and have been used by state Medicaid programs for many years. Restricted recipient programs limit an individual to receiving their controlled substance prescriptions from one prescriber and one pharmacy for allowed insurance payment, or else the individual must pay cash. These interventions have demonstrated some positive impacts at the state level, including reduced use of controlled substances and emergency room visits as well as cost savings.^{118,119}

Many PBMs also perform prescription claims reviews using software algorithms to identify prescribers, pharmacies, or patients who may be using opioids unsafely or else potential fraudulently prescribing, dispensing or using opioids. For example, PBMs may perform retrospective analyses to identify members visiting multiple prescribers or pharmacies, exceeding a threshold of morphine milligram equivalent (MME) daily or filling multiple simultaneous controlled substance claims. Since PBM surveillance criteria are proprietary, little is known regarding their validity, such as how closely they are associated with opioid-related injuries, deaths, health care use, or spending. However, some information about specific criteria used in select PBM interventions has been published.^{120,121,122}

The Centers for Medicaid and Medicare Services (CMS) implemented an approach to identify high-dose and potentially unsafe opioid use in 2013. The criteria identify beneficiaries using high doses of opioids (>120 MME) for 90 or more consecutive days and also those who are receiving opioids from four or more prescribers and four or more pharmacies. Plans must implement utilization review and case management, usually performed by the PBM, for the identified beneficiaries and report back to CMS.¹²³ The non-profit Pharmacy Quality Alliance has also developed several quality metrics aimed at the opioid epidemic including one focused on the use of opioids at high dosage in persons without cancer. This measure was included in the Medicaid Adult Core Set of measures in 2016.¹²⁴ PBMs can use CMS and Pharmacy Quality Alliance criteria to identify at-risk members across their insured lives.

While more expensive and complicated to administer, payers and PBMs also have employed more intensive treatment programs for patients with opioid-use disorders and frequent health care use. For example, one payer implemented a Behavioral Health Medication Assistance Program that consisted of nurses and psychologists working with physicians to evaluate members at risk or in treatment for an opioid-use disorders. While impressive gains were reported, such as a 35 percent reduction in hospital admissions, as with many other analyses, these evaluations were based on proprietary data subject to several limitations.¹²⁵ Another PBM utilized a managed care pharmacist to implement a prescriber controlled substance intervention and reported a four to one return on investment.¹²⁶

ENGAGING PHARMACY BENEFITS MANAGERS AND PHARMACIES

In one synthesis of the effect of insurer and PBM strategies to address opioid overuse, most studies examined some combination of patient review and restriction programs, drug utilization review programs, or prior authorization and quantity limit programs.¹²⁷ These assessments usually evaluated the effect of such programs on cost savings and changes in utilization; analyses of the effect of these strategies on health outcomes was rare. Many of these programs demonstrated significant reductions in the outcomes examined, such as the mean number of controlled substance claims, long-acting opioid prescriptions, carisoprodol prescriptions, and overall rates of opioid and sedative use. Despite this, studies were of low quality, often because of the absence of suitable comparison groups, long-term follow-up, and robust methods to address the potential for unmeasured confounding or co-interventions.¹²⁸

Pharmacies also are an important stakeholder in the health care supply chain and distribution system for prescription opioids in the United States. Pharmacies' resources, programs, and policies vary across different types of pharmacies including retail chain pharmacies, mass retailers, food stores, and independent, government, and clinic-based pharmacies. State and federal law govern some elements of their conduct with respect to reducing non-medical opioid use and diversion. For example, the removal of prescriber dispensing privileges to curtail both diversion and inappropriate opioid prescribing is feasible and supported by state and federal law. Such actions are quite rare, yet given the high volume of opioids accounted for by a small group of prescribers, these actions may nevertheless have an important impact on the overall volume of controlled substances dispensed.¹²⁹ Both the Drug Enforcement Agency and state boards of pharmacy require pharmacists to use sound professional judgment when determining whether to fill opioid prescriptions.

Both PBMs and pharmacies play an important role in the increasing prevalence of electronic prescribing. Electronic prescribing for opioids has the potential to reduce forgery and fraudulent controlled substance prescriptions.¹³⁰ In 2016, fewer than 15 percent of the U.S. controlled substance prescriptions were electronically prescribed.^{131,132} New York's Internet System for Tracking Over Prescribing (I-STOP) law was enacted in March 2016 and facilitated a 54 percent increase in electronic prescribing of controlled substances during 2016. Additional laws and evaluations to monitor their impact will be critical to maximizing the use of electronic prescribing as a tool for more effectively controlling the prescription opioid supply.

Many of the practices identified above, ranging from PBMs utilization management programs to pharmacy education programs, can be potentiated by the accessibility of PDMP data, since such data allows for a unified and comprehensive view of patients' prescription opioids prescribed as well as the ability to identify and personalize clinical outreach for specific patients based on their risk of potential injury or death from prescription opioids. The role of PDMPs in reducing non-medical opioid use and diversion is addressed in Section 1, including the interface between PDMPs, PBMs, and pharmacies. These interfaces have also been discussed elsewhere.^{133,134}

Although not widely enacted, "take-back" programs that foster safer medication disposal by allowing for patients to return unused or unwanted opioids may also help to reduce the potential for diversion of opioids from licit to illicit channels. Pharmacies provide a convenient site for individuals to dispose of their unused opioid prescriptions, and recent federal law has clarified the legal framework in support of such activities. Evidence supporting the effectiveness of allowing pharmacies to take back and destroy prescription drugs is anecdotal, and additional discussion regarding these programs is presented in Section 5 of this report.

RECOMMENDATIONS FOR ACTION

3.1 INFORM AND SUPPORT EVALUATION RESEARCH OF PBM AND PHARMACY INTERVENTIONS TO ADDRESS THE OPIOID EPIDEMIC

PBMs and pharmacies are engaged in opioid interventions. Research is needed to evaluate the clinical and economic impact of these efforts. A stakeholder meeting to review research that is in progress and to identify priorities for new research is needed to inform investment in this area.

Rationale: Without high-quality evaluations of interventions, PBMs and pharmacies will lack a reliable evidence-base to inform how best to invest prevention dollars.

Current Status: The Patient-Centered Outcomes Research Institute (PCORI) has no funded projects on this topic. The CDC and the National Institute on Drug Abuse (NIDA) have sponsored modest extramural funding in this area. The private sector conducts research, much of which goes unpublished.

ENGAGING PHARMACY BENEFITS MANAGERS AND PHARMACIES

3.2 CONTINUE THE DEVELOPMENT AND ENHANCEMENT OF EVIDENCE-BASED CRITERIA TO IDENTIFY INDIVIDUALS AT ELEVATED RISK FOR OPIOID-USE DISORDERS OR OVERDOSE, AND OFFER ADDITIONAL ASSISTANCE AND CARE TO THESE PATIENTS

The Centers for Medicaid and Medicare Services (CMS) and the Pharmacy Quality Alliance have developed criteria to identify beneficiaries using high doses of opioids or using opioids in a high-risk manner, such as concomitantly with benzodiazepines. PBMs should be encouraged to use CMS and Pharmacy Quality Alliance criteria to identify at-risk members across their insured lives and to create evidence-based clinical programs for member or prescriber outreach.

Rationale: Criteria currently used to identify individuals at high risk for an opioid-use disorders or overdose require further refinement and validation.

Current Status: State Medicaid, managed care plans, and PBMs are using varying methods with varying degrees of evidence to support efforts to identify and respond to at-risk individuals.

3.3 IMPROVE MANAGEMENT AND OVERSIGHT OF INDIVIDUALS WHO ARE PRESCRIBED OPIOIDS FOR CHRONIC NON-CANCER PAIN

Encourage the states and CMS to incentivize PBMs through the Medicaid Innovation Accelerator Program and CMS Innovation Center to implement and rigorously evaluate innovative medication management strategies consistent with the CDC Guideline¹³⁵ for targeted management of individuals prescribed opioids for chronic non-cancer pain.

Rationale: Managed care plans and PBMs are uniquely positioned to implement utilization management programs for ensuring safe opioid prescribing consistent with the CDC Guideline.

Current Status: A systematic assessment of how plans and PBMs are currently implementing and evaluating management and oversight of individuals who are prescribed opioids for chronic pain does not exist.

3.4 SUPPORT RESTRICTED RECIPIENT (LOCK-IN) PROGRAMS AMONG SELECT HIGH-RISK PATIENT POPULATIONS

PBMs and plan sponsors should be encouraged to implement restricted recipient programs among select, high-risk patient populations in commercial, Medicaid, Medicare Advantage, and Part D plans.

Rationale: Lock-in programs among high-risk populations have demonstrated to be successful among select Medicaid programs. For high-risk patients, such programs offer an opportunity to enhance the coordination and quality of their care.

Current Status: In June 2016, the Comprehensive Addiction and Recovery Act (CARA) was signed, which included “lock-in” provisions for at-risk Part D beneficiaries. As of December 2016, the Department of Health and Human Services was determining the criteria for such programs.

3.5 IMPROVE MONITORING OF PHARMACIES, PRESCRIBERS, AND BENEFICIARIES

All PBMs should provide a list of pharmacies, prescribers, and beneficiaries to the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) that meet a threshold of concern for opioid prescribing. Based on these reports, MEDICs should share information about providers of concern with CMS.

Rationale: This information exists and can be used to address possible sources of diversion.

Current Status: Most PBMs are providing a list of pharmacies, prescribers, and beneficiaries that meet certain criteria of concern to NBI MEDIC. CMS is engaged with some follow-up of this information.

4. IMPLEMENTING INNOVATIVE ENGINEERING STRATEGIES

The U.S. Food and Drug Administration (FDA) highlighted the potential for innovative packaging solutions to be a part of the Agency's response to the role of prescription opioids in opioid-use disorders when it published a notice for public comment in the Federal Register in April 2014. Prescription packaging designs have evolved significantly in the past decade and now include many features—such as electronic systems for monitoring, accessing, and improving adherence to medication regimens—that also could help to prevent the diversion of prescription opioids. Examples of design strategies cited in the FDA notice include: prescription dispensing systems that remind patients to take a dose, track when a dose is taken, and limit further access until the next dose is due; radio-frequency identification-based systems; and microchips embedded within tablets. Often these technologies are packaged with data capture systems to provide feedback to providers on adherence, use, and tampering.¹³⁶

The FDA has continued to examine packaging, storage, and disposal systems to enhance opioid safety, such as through a public and private sector workshop that was held in June 2017.¹³⁷ The group that was convened identified several promising packaging, storage, and disposal mechanisms including: locking technologies, disposal pouches, and calendarized blister packs for households with children; and calendarized blister packs, RFID-enabled monitoring, and dispensing technologies for adult patients. The summary report concludes:

*“Building on injury prevention principles, a combination of passive protections, such as abuse deterrent drug formulations, and safety enhanced packaging, storage, and disposal solutions, may significantly help to improve the safe use of prescribed opioids. ... To maximize the likelihood of a positive impact, experts thought that solutions should be passive, cost-effective, supported by payers, and appealing to patients, providers, and pharmacists alike, without imposing excess burden.”*¹³⁸

Although most prescription drug packaging innovations have been designed to improve medication compliance among patients using non-controlled substances for chronic conditions,^{139,140} they could be adapted to help prevent prescription opioid misuse and diversion. For example, these products could reduce serious complications such as overdose by facilitating appropriate dosage and administration, and could help providers monitor for signs of non-medical use or diversion. In addition, products that limit access to the medication during non-dosing periods could help prevent use of the medication by non-prescribed individuals. The concept of personalization, i.e., use of a personal identification number, radio-frequency device, or fingerprint, facial recognition or other biometrics, has been proposed to prevent other types of injuries¹⁴¹ and could be applied to prescription drug packaging as well. A pill dispenser that requires the prescribed patient's fingerprint before releasing the appropriate pain medication at the appropriate time, is an example of an application of personalized technology to prevent misuse and diversion through theft.

Evidence about the effectiveness of packaging designs to prevent non-medical prescription drug use and diversion is limited. One study of 37 individuals assessed the impact of an electronic medicine dispenser on diversion of buprenorphine-naloxone among patients being treated for opioid addiction. Researchers documented that 68 percent of patients receiving the dispenser preferred to use the electronic dispenser to store their tablets compared to the traditional prescription container; 16 percent reported that the dispenser prevented them from diverting their buprenorphine; 23 percent stated the dispenser prevented others from diverting their buprenorphine; and 58% believed the dispenser could prevent diversion of the medications dispensed in the electronic device. Additionally, 19 percent described the dispenser as “difficult” to tamper with while 58 percent described tampering with the dispenser as “impossible”.¹⁴² Another product, which couples a flow-controlled, tamper-resistant medication dispenser with an internet and phone accessible treatment portal, demonstrated sufficient promise to obtain funding from the National Institute on Drug Abuse. A phase II randomized controlled trial will assess use of the device and opioid misuse among patients from two pain management clinics.¹⁴³ Results from this trial were not available as of June 2017.

A review of the currently available and in-development opioid packaging designs concluded that many of the commercialized technologies such as locking caps, tamper-proof packages, and pill-dispensing products are most likely to deter unintentional misuse by elderly people or children and have limited application to prevent intentional misuse.¹⁴⁴ However, newer technologies, such as radio-frequency identification wireless technologies and simple technologies combined with radio-frequency identification—as well as other types of smart technologies—have the potential to play a role in deterring intentional opioid misuse by increasing communication between health care professionals and patients. The feasibility and differential impact of “tamper-resistant” rather than “tamper-evident” technologies has yet to be explored, but is a highly relevant question because of the intentional misuse issue. As part of their senior mechanical engineering design course, students at Johns Hopkins University created a prototype of a tamper-resistant, personalized dispenser that uses fingerprint recognition technology and is programmed to deliver a one-month supply of an opioid in the right time and correct dosage. The product is designed

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so that only a pharmacist can open and lock the device. At the time of this report, this product was still in the prototyping and testing phase.¹⁴⁵

Despite the very limited data on effectiveness, there are several products on the market for consumer use, and several state legislatures are considering bills requiring locking pill vials or similar technology. There is a need for research to understand the impact of these products on prescription drug misuse and diversion, their impact on rates of opioid-use disorders and opioid overdoses, and how they are used by people prescribed opioids for pain management. In addition to research questions on effectiveness, there are several outstanding questions that need to be explored before widespread adoption of these products can occur. These questions include:

- Where will these products enter the medication prescribing and use process? Will they be available for home use? Will pharmacists use them instead of traditional pharmacy dispensing vials? Will manufacturers move away from bulk product distribution, and incorporate these packaging designs for direct dispensing from the doctor's office or pharmacy?
- How will these products be regulated (e.g., as consumer products, medical devices, as combination drug devices)?
- Who will take on the costs for these products? Pharmacies? Patients? Insurers/PBMs?
- Who will control, monitor, and have access to the data available from these devices?

An additional design strategy to reduce non-medical use and overdose of prescription opioids is through the development of products designed to deter misuse. FDA, the pharmaceutical industry, Congress, and other stakeholders have called on drug developers to create opioids that are designed to make tampering and manipulation more difficult. To encourage product development, FDA has held multiple public meetings and issued guidance to industry. In April 2015, FDA issued a final guidance to assist industry in the development of opioid products with abuse deterrent features. The guidance explains FDA's current perspective on the types of studies that should be conducted to demonstrate that a given formulation can be expected to deter abuse by particular routes, and makes recommendations about how those studies should be performed and evaluated.¹⁴⁶

Although FDA has approved labeling for 10 opioid analgesic products to indicate that they have design features intended to make non-medical use, typically via intranasal and injection routes, more difficult, FDA has concluded that misuse is still possible, and no products have been given a labeling claim for reducing opioid-use disorders or overdose deaths. Moreover, FDA has not granted a labeling claim for any product indicating that the product has demonstrated abuse-deterrence in a real-world setting. In fact, at a July 2017 meeting FDA stated:

*"Determining the real-world impact of opioid formulations with properties designed to deter abuse is a key next step in understanding the utility of these products [abuse-deterrent formulations] in helping to curb the opioid abuse epidemic."*¹⁴⁷

It is important to examine both the potential intended and unintended consequences of reformulated products. For example, in June 2017, the FDA requested that Endo Pharmaceuticals remove its reformulated product, extended-release oxycodone (Opana ER), from the market due to post-marketing data demonstrating a significant shift in the route of non-medical use of Opana ER from intranasal to injection use after the product was reformulated.¹⁴⁸ The reformulated version was associated with a large HIV outbreak in Scott County, Indiana in 2015¹⁴⁹ as well as cases of thrombotic microangiopathy.¹⁵⁰ Additional questions have been raised regarding the ways that abuse deterrent-formulations have been marketed and promoted,¹⁵¹ their costs¹⁵² as well as unintended consequences including misperceptions that they may be less addictive or more effective than their non-abuse deterrent counterparts.^{153,154} Regarding these products as "tamper-deterrent" rather than "abuse-deterrent" might help to reduce these misperceptions and unreasonable expectations about what these products can and cannot deliver, and their ultimate effect on the opioid epidemic.

Thus, while modified formulations that discourage non-medical use represent a promising technology, many questions regarding their real-world effectiveness as well as potential for unintended harms remain.

IMPLEMENTING INNOVATIVE ENGINEERING STRATEGIES

RECOMMENDATIONS FOR ACTION

4.1 CONTINUE TO SUPPORT STAKEHOLDER MEETINGS TO ADVANCE TECHNOLOGICAL SOLUTIONS

Work with the FDA to continue engaging with stakeholders to advance the conversation about packaging designs, and to identify high-priority future directions for engineering-related solutions and implementation of existing technologies.

Rationale: Engineering solutions to deter non-medical use of prescription opioids are promising and under development. There is a need for coordination of and support for the current efforts to ensure this line of innovation is adequately supported, quickly brought to market and rigorously evaluated.

Current Status: The FDA has convened one such meeting through the Duke-Margolis Center for Health Policy.

4.2 SPONSOR DESIGN COMPETITIONS

Partner with stakeholders to develop design competitions to incentivize innovative packaging and dispensing solutions.

Rationale: Design competitions have been used to encourage and support innovation in many areas. Engineering strategies for prescription packaging are a logical candidate for such a competition

Current Status: We are unaware of any design competitions on this subject.

4.3 SECURE FUNDING FOR RESEARCH TO ASSESS THE EFFECTIVENESS OF INNOVATIVE PACKAGING AND DESIGNS AVAILABLE AND UNDER DEVELOPMENT

Rationale: Data on the effectiveness of packaging interventions is limited. Research is needed to evaluate the engineering innovations under development and to inform future development.

Current Status: We are unaware of any funding source dedicated to evaluating engineering designs for prescription packaging.

4.4 USE RESEARCH TO DEVELOP IMPLEMENTATION STRATEGIES IN ADVANCE OF IDENTIFICATION OF EFFECTIVE PRODUCTS

Engage with key stakeholders, such as product developers, drug manufacturers, pharmacies, payers, regulators, chronic opioid therapy patients, and the public to explore potential barriers and incentives to product uptake.

Rationale: Innovations in prescription packaging are promising, but little is known about how to ensure the public will use these products and that the products will be integrated into existing payment policies. Research is needed to ensure that these aspects of translation are understood.

Current Status: We are unaware of any efforts to gather empirical data about how to ensure innovative engineering packaging for prescriptions is effectively integrated into the consumer market.

4.5 WORK WITH INDUSTRY AND GOVERNMENT AGENCIES TO IDENTIFY OPPORTUNITIES FOR THE DEVELOPMENT AND RIGOROUS EVALUATION OF ABUSE-DETERRENT FORMULATIONS OF PRESCRIPTION OPIOIDS

Rationale: Many formulations carry the potential for non-medical use, via intravenous injection, nasal inhalation, or other means. Development of drugs that deter this type of misuse may help limit the extent of and harms related to prescription opioid misuse.

Current Status: Previous abuse-deterrent formulations have shown limited effectiveness in terms of reducing abuse potential.¹⁵⁵ Future efforts must deter use by nasal inhalation as well as injection and oral routes if they are to be widely effective.

5. ENGAGING PATIENTS AND THE GENERAL PUBLIC

Much of this report emphasizes recommendations for changing prescriber behavior, reducing the supply of opioids, providing opioid-use disorders treatment, and decreasing the likelihood of overdose among those who are already using opioids. Here we focus on efforts to engage with patients and the general public to better understand opioid risks and alternatives for pain management. We also consider how we can collectively work to reduce opioid demand for the treatment of acute and chronic non-cancer pain, to promote safer use, and to minimize the widespread availability of these medicines for non-medical use.

Using clinical interactions to educate patients about the risks of prescription opioids and alternatives to pain management are beginning to be explored, but the literature is scant. Included in this effort are opioid treatment agreements, although there is a lack of evidence of their effectiveness in reducing opioid misuse and promoting adherence. Ethical issues regarding the use of patient contracts have also been raised, including concerns that they may harm the patient-provider relationship, further stigmatize opioid use,¹⁵⁶ or misconstrue the ability to prevent addiction. A recent multi-center trial of the patient provider agreement created by the Food and Drug Administration's Safe Use Initiative found that 94 percent of patients, but only 42 percent of providers, rated the tool as helpful, and there were no opioid-use related outcomes reported.¹⁵⁷

The emergency department is another setting in which patient education regarding opioids is relevant¹⁵⁸ although there is limited research. One intervention study demonstrated that correct recall of instructions for taking analgesics increased from 40 percent to 71 percent after the introduction of written discharge instructions,¹⁵⁹ and a descriptive study found that none of the 20 patients discharged from an emergency department with an opioid prescription reported storing or disposing of them safely.¹⁶⁰ An ongoing project is testing the use of an m-Health patient decision aid in two emergency departments in Baltimore, Maryland and Morgantown, West Virginia.¹⁶¹ Patients completed a personalized and tailored decision aid about pain treatment options and were encouraged to discuss the results with their doctor. Results of a small randomized trial found that the intervention effects were in the expected direction for knowledge, decisional conflict, and preference for a non-opioid approach to pain management.¹⁶² Reductions in decisional conflict were statistically significant, although shared decision making and actual prescribing were not. More research is needed on how patient education can best facilitate patient empowerment, shared decision making, and a reduced demand for prescription opioids in managing pain.

Interventions at the community level have not been widely promoted as part of the national approach to controlling this epidemic. However, efforts to raise awareness about the risks associated with prescription opioids and alternatives available for pain management through public education campaigns are underway, including: The Medicine Abuse Project, aimed at preventing teen non-medical use and promoting treatment; Rx for Understanding, a school-based curriculum; the JED Foundation's college campus initiative; and the National Institutes on Drug Abuse's PEERx program. In 2017, the CDC has launched "It Only Takes a Little To Lose a Lot" Rx Awareness Campaign, which features testimonials of people affected by the epidemic as well as materials for others who want to implement their own consumer-directed campaigns. Assuring that public education initiatives are appropriately targeted, informed by evidence and rigorously evaluated is critically important to assuring that investments are well placed and effective.

Raising awareness is generally viewed as an important strategy for addressing prescription opioid-use disorders, and offers an opportunity for prevention when combined with other strategies. Best practices in health promotion and public health suggest that awareness-raising efforts will have maximum impact when combined with other interventions that address the larger context in which the problem is occurring. For this issue, raising awareness could be enhanced with attention to the policy context, such as naloxone availability as well as the need for other services, such as treatment for opioid-use disorders.

In response to increasingly high rates of unintentional opioid overdose deaths in Staten Island, New York, the city health department launched a comprehensive five-part public health strategy beginning in 2011. This included: creating and promoting prescribing guidelines; media outreach; town hall meetings; public service announcements; and enacting a law requiring the use of the State's PDMP. As a result, there was a 29 percent decrease in the opioid overdose death rate in Staten Island from 2011 to 2013, and no change in the other four New York City boroughs.¹⁶³

Project Lazarus is a community-based initiative in North Carolina, in which 74 of 100 counties participated by implementing up to seven interventions: community education; provider education; hospital emergency department policies limiting prescribing and requiring PDMP use; training law enforcement in diversion control; programs to support pain patients; naloxone distribution; and addiction treatment. Interrupted time-series evaluation design estimated rates of unintentional and undetermined overdose deaths and emergency department visits during pre-intervention (2009–2012) and intervention periods (2013–2014). Provider education and policies limiting emergency department prescribing were associated with lower overdose mortality, although the

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latter was also associated with more emergency department visits. Expansions of opioid agonist treatment were associated with increased mortality, but fewer emergency department visits.¹⁶⁴

Public engagement efforts should be cognizant of the landscape of opioid use, sharing, storage, and disposal in U.S. homes. There are many deficiencies in how prescription opioids are stored and disposed of.¹⁶⁵ In a national survey of adults recently prescribed an opioid, more than one-fifth (21%) reported having shared it with another person. Few respondents stored the medication in a locked or latched place (21%), and among those with leftover opioid medications, 61 percent reported keeping them for future use. Nearly half of the adults with recent opioid medication use did not recall receiving information on safe storage (49%) or proper disposal (45%).¹⁶⁶ Only 12 percent of homes in which older children and teenagers were living had their opioids stored safely.¹⁶⁷ According to the 2015 National Survey on Drug Use and Health, more than half of the 969,000 12- to 17-year-olds who reported misusing prescription pain medicine cited a friend or relative as the source, and nine percent said they took the pills without asking, almost twice the proportion who reported buying pills from a drug dealer (5%).¹⁶⁸

In 1995, CDC launched the National Campaign for Appropriate Antibiotic Use in the Community, which was renamed “Get Smart: Know When Antibiotics Work”. One aim of the campaign was to decrease the demand for antibiotics by adults and parents of children with upper respiratory viral infections. Multiple studies have demonstrated positive impacts, suggesting that improving patient knowledge of risks, benefits, and alternatives to treatment may be a promising approach to reducing the number of prescriptions written.¹⁶⁹ Further studies have investigated the effectiveness of computerized patient education modules promoting awareness of appropriate antibiotic use, and provided initial evidence that these interventions can be effective in reducing demand.¹⁷⁰ For community prevention efforts, there are many parallels to the prescription opioid problem—i.e., the drugs are useful in certain circumstances but over-prescribed in many others, and patients are generally unaware of the potential individual and societal impacts associated with over-prescribing. Thus, community prevention interventions would do well to draw from the strategies used to reduce antibiotic overuse.

RECOMMENDATIONS FOR ACTION

5.1 CONVENE A STAKEHOLDER MEETING WITH BROAD REPRESENTATION TO CREATE GUIDANCE THAT WILL HELP COMMUNITIES UNDERTAKE COMPREHENSIVE APPROACHES THAT ADDRESS THE SUPPLY OF, AND DEMAND FOR PRESCRIPTION OPIOIDS IN THEIR LOCALES; IMPLEMENT AND EVALUATE DEMONSTRATION PROJECTS THAT MODEL THESE APPROACHES.

Rationale: Attention to the complex social and political context in which the problem of prescription misuse and overdose occurs has not been reflected in existing community campaign efforts. Broader stakeholder engagement may yield impactful new approaches.

Current Status: There are now several reports in the literature of community campaigns, some have evaluation data and others do not.

5.2 CONVENE AN INTER-AGENCY TASK FORCE TO ASSURE THAT CURRENT AND FUTURE NATIONAL PUBLIC EDUCATION CAMPAIGNS ABOUT PRESCRIPTION OPIOIDS ARE INFORMED BY THE AVAILABLE EVIDENCE, AND THAT BEST PRACTICES ARE SHARED

Rationale: Past success with reducing antibiotic use is generally attributed to a comprehensive national campaign. Applying lessons learned from that success to the current prescription opioid challenge will increase the likelihood that public education strategies benefit from the available evidence.

Current Status: Public education about the risks of prescription opioids and alternatives for pain management is needed, and many efforts are underway and will likely be developed. The extent to which these efforts are informed by the available evidence is unknown, and there is no central repository for collecting this evidence and sharing best practices.

ENGAGING PATIENTS AND THE GENERAL PUBLIC

5.3 PROVIDE CLEAR AND CONSISTENT GUIDANCE ON SAFE STORAGE OF PRESCRIPTION OPIOIDS

Rationale: The most common source of prescription opioids for non-medical purposes is family and friends, and national data indicate that one in five patients prescribed an opioid has shared it. National survey data reveal that very few parents with older children and teens keep their opioid prescriptions in a locked place. Ensuring prescription medications are not easily accessible may reduce intentional misuse by teens and adults and unintentional misuse by young children.

Current Status: While engineering solutions to packaging hold great promise, as detailed earlier in this report, clear guidance about safe storage options for patients who bring prescription opioids home is needed. National survey data reveal that nearly one-half of patients given an opioid prescription are given no information about safe storage. Messages should be appropriate for all populations, including those with low literacy and non-English speakers, and should be consistent across all sources—the prescriber, the pharmacist, in the patient packaging materials, and in community campaigns.

5.4 PROVIDE CLEAR AND CONSISTENT GUIDANCE ON SAFE DISPOSAL OF PRESCRIPTION OPIOIDS AND EXPAND TAKE-BACK PROGRAMS

Rationale: There are enormous volumes of unused opioids in homes throughout the U.S. that are too often diverted for non-medical use. Safe disposal options for prescription opioids are needed. Guidance from the federal government about how to safely dispose of prescription opioids can serve to launch community-based take-back initiatives that are responsive to local needs and culture.

Current Status: National survey data reveal that nearly one-half of patients given an opioid prescription receive no information about disposal options. Some pharmacies are taking back opioids. However, pharmacies are not universally providing this service or advertising this service to their patients. The Comprehensive Addiction and Recovery Act of 2016 expanded funding for take-back programs, but clear guidance on how to safely dispose of prescription opioids is lacking. Access to take-back programs is also limited and highly variable across jurisdictions. Messages should be appropriate for all populations, including those with low literacy and non-English speakers, and should be consistent across all sources—the prescriber, the pharmacist, in the patient packaging materials, and in community campaigns.

Identifying and Treating People with Opioid-Use Disorders

IDENTIFYING AND TREATING PEOPLE WITH OPIOID-USE DISORDERS

“Addiction is defined as a chronic, relapsing brain disease that is characterized by compulsive drug seeking and use, despite harmful consequences. It is considered a brain disease because drugs change the brain; they change its structure and how it works.”¹⁷¹ Like many other chronic illnesses, addiction is influenced by genetics, the environment, and behavior. Also, like many other chronic illnesses, addiction is treatable.

In fact, opioid-use disorder is quite responsive to opioid agonist therapy, defined by the U.S. Surgeon General as a “combination of behavioral interventions and medications to treat substance-use disorders.”¹⁷² The Surgeon General has found that “[s]tudies have repeatedly demonstrated the efficacy of [opioid agonist treatment] at reducing illicit drug use and overdose deaths, improving retention in treatment, and reducing HIV transmission.”¹⁷³ Indeed, in many studies, well more than half of patients receiving opioid agonist treatment show substantial improvement.¹⁷⁴ Communities that have expanded access to opioid agonist treatment have seen reductions in overdose deaths and other measures of population health improvement.¹⁷⁵

Despite these facts, there are a variety of barriers that impede our nation’s ability to identify and provide high-quality treatment to those with opioid use disorder. First, there is limited data available to track the opioid epidemic and the availability of treatment services in many areas. Overdose mortality surveillance depends on a patchwork system of medical examiners and coroners who do not use a consistent approach to classify cause of death. As a result, localities face difficulties developing an accurate picture of the epidemic and assessing whether intervention strategies are having the intended effect.

Second, there is inadequate access to opioid agonist treatment, which includes treatment that uses methadone and buprenorphine (a third FDA-approved treatment, naltrexone, is an opioid antagonist). Many people with opioid-use disorder do not receive treatment at all, and among those who do, just over a quarter received treatment with methadone or buprenorphine, the medications for opioid-use disorder with the strongest evidence of effectiveness.¹⁷⁶ Inadequate access is related to poor insurance reimbursement,¹⁷⁷ high regulatory barriers for methadone,¹⁷⁸ and relatively few prescribers of the medication buprenorphine.¹⁷⁹ Even among those receiving treatment, relapse is not uncommon,^{180,181} reflecting the importance of high-quality, comprehensive, longitudinal care that is integrated with the other health care that patients receive.

Third, many people who use opioids for non-medical purposes die of overdose before they are able to reach treatment. An evidence-based strategy to address this challenge is greater availability of the overdose reversal drug, naloxone – for people who use opioids, for friends and family, for law enforcement, and for the general public.¹⁸² As of July 2017, the Network for Public Health Law reports that all 50 states and the District of Columbia have passed laws to facilitate access to naloxone, and 40 states and the District of Columbia have Good Samaritan laws in place that provide some legal protections for people who respond to overdose events in good faith.¹⁸³ However, the high cost of naloxone and resistance in some communities is slowing the diffusion of this strategy.¹⁸⁴

Fourth, the United States has been slow to pursue opportunities to engage people in the throes of addiction, provide lifesaving services, and support their transition to treatment. Despite strong evidence supporting syringe and needle exchange in reducing HIV and providing a path to addiction treatment, the federal prohibition on funding for these services only recently ended.¹⁸⁵ In Europe and Canada, it has been demonstrated that supervised consumption spaces reduce overdose in the surrounding community and provide a path to engagement and care for those not in treatment.¹⁸⁶ There is growing interest among U.S. localities in establishing supervised consumption spaces,¹⁸⁷ but questions about whether federal law enforcement will permit them to operate remain.

Finally, the immense stigma of addiction, opioid-use disorder, and its treatment creates many obstacles for integrating treatment into clinical care. Stigmatizing attitudes among the public and policymakers reduce support for policies to expand opioid-use disorder treatment, and stigma is also a barrier to treatment seeking for individuals with opioid-use disorders. Stigma is reflected in the derogatory language used to reference individuals suffering from opioid-use disorder;¹⁸⁸ in the ideology – common among many in the addiction treatment world – that one cannot receive medication to be in recovery; in the reluctance of traditional medical treatment providers to offer services; and in the use of law enforcement strategies unthinkable for other chronic illnesses, such as rulings by judges that prohibit individuals from receiving evidence-based treatment.¹⁸⁹

These challenges are not the only ones facing those who are at risk of or who have an opioid-use disorder. While beyond the scope of this report, there has also been inadequate attention to the factors that may promote or protect against this brain disease, including intergenerational factors,^{190,191} trauma,¹⁹² and resilience.^{193,194} In addition, there are a variety of supports that those with addiction may benefit from to maintain a stable recovery. These include employment, housing, health care, peer support, and other services. Even where such services exist, it can be difficult to develop strategies that account for the potential for relapse, such as what to do for individuals when they violate terms of zero drug tolerance while living in supportive sober housing. Expansion of recovery support is urgently needed, along with research designed to answer key questions about how to best help people move past their addiction, and into healthy and productive lives.

6. IMPROVING SURVEILLANCE

The opioid epidemic is rapidly changing, and active surveillance is vital. For example, early in the epidemic deaths were primarily due to prescription opioids. Between 2014 and 2015, deaths associated with the synthetic opioid fentanyl increased by a staggering 72 percent nationwide with even greater increases reported in states the following year. Fentanyl-related deaths in Maryland increased 229 percent between 2015 and 2016, marking the single greatest increase in drug-related deaths in the history of that state.^{195,196}

Despite these disturbing trends, epidemiologic data are usually dated, posing an additional challenge for public health officials, policymakers, service providers, and other stakeholders to effectively intervene. Real-time surveillance of the populations at risk, types of drugs being used by people with opioid-use disorders and specifically used in overdose events, and geographic distribution of the problem are needed to reverse the current trend.

Various state-led efforts have attempted to address the need for real-time surveillance, though most are limited to data reflecting opioid-related hospitalizations and/or deaths. In 2014, the Rhode Island Department of Health, with support from the state legislature, launched an opioid surveillance system that requires emergency departments to report all cases of opioid overdose within 48 hours.¹⁹⁷ The goal is to identify outbreak clusters in real-time in order to design and implement responsive, targeted interventions. The system also has the capacity to identify geographically specific risk factors that can inform response and prevention. In the first full year of data collection, this system captured 1,523 hospital-reported adult overdose events, and identified socio-demographic risk factors as well as drug- and treatment-specific data, which can inform hospital, city, and state policies.

In the Fall of 2016, CDC announced a 12-state, \$12.8 million dollar effort to support state-based opioid surveillance systems. The project, which includes Kentucky, Maine, Massachusetts, Missouri, New Hampshire, New Mexico, Ohio, Oklahoma, Pennsylvania, Rhode Island, West Virginia, and Wisconsin, is designed to enhance the timeliness of collection and dissemination of data on fatal and non-fatal opioid overdoses to better inform time-sensitive state and national prevention and response efforts.¹⁹⁸

Other surveillance efforts, relying on data sources such as emergency medical services (EMS) transportation, hospital and emergency administrative data, PDMPs, and death certificates, have produced varying levels of detail.^{199, 200, 201} Such systems, however, often operate at a delay of several months to a year or more, limiting their usefulness as a tool for timely surveillance and response.

RECOMMENDATIONS FOR ACTION

6.1 INVEST IN SURVEILLANCE OF OPIOID MISUSE AND USE DISORDERS, INCLUDING INFORMATION ABOUT SUPPLY SOURCES

Surveillance of opioid use, misuse, and opioid-use disorders helps to quantify the size and characteristics of the population that is at-risk for adverse outcomes related to opioid use. Such data in turn can allow us to understand the effectiveness of prevention programs and allocate resources for harm reduction and treatment. The National Survey of Drug Use and Health (NSDUH) is a household survey that measures use of opioids and other substances and screens for use disorders. In 2015 it was revised so that it now collects more data related to prescribed opioid pain reliever use as well as non-medical use, and motivations for non-medical use. The NSDUH remains the sole national survey to assess symptoms of opioid-use disorders in the population on an annual basis. The NSDUH has limitations, however, such as under-coverage of high-risk groups including incarcerated and homeless individuals, and a lack of geographic identifiers in public use files. Improving epidemiological surveillance will require additional efforts to strengthen the NSDUH and investments in complementary sentinel surveillance systems. This effort will involve collaboration with the Substance Abuse and Mental Health Services Administration and the CDC. Greater behavioral surveillance will inform understanding of both the use of opioid drugs and treatment services.

Rationale: Surveillance of opioid use, misuse, and opioid-use disorders is critical for the improvement of primary, secondary, and tertiary prevention efforts. Revising an existing surveillance tool is a cost-effective way to obtain needed information.

Current Status: Several federally-supported data collection efforts have attempted to monitor trends in opioid-use disorders with varying degrees of success. Few (e.g., RADARS) have proactively measured addiction prevalence from a variety of sources.²⁰² Investing in these tools will be critical to improving prevention efforts. For example, there is a need to revive programs that screen arrestees for opioid use, such as was historically provided by the Arrestee Drug Abuse Monitoring (ADAM) Survey, and to add more surveillance of opioid use and misuse to national surveys other than the NSDUH. Data from prescription drug monitoring programs provides another tool to quantify prevalence of prescribed opioid use, but does not necessarily indicate where misuse is occurring or capture use of opioids through diversion.

IMPROVING SURVEILLANCE

6.2 DEVELOP AND INVEST IN REAL-TIME SURVEILLANCE OF FATAL AND NON-FATAL OPIOID OVERDOSE EVENTS

Fatal and non-fatal overdoses are key indicators of the scope and lethality of the opioid epidemic. However, there are known data collection challenges that make timely, consistent, and longitudinal assessment of overdose events problematic. The most widely reported outcome is the national overdose death rate, yet this rate is inconsistently measured across areas and does not capture non-fatal overdoses.

Rationale: Real-time surveillance of all overdose events will help to inform appropriate responses to prevent overdose events and deaths, and can help to address fundamental questions about the epidemic such as the number of individuals who are switching to products with fentanyl adulterants.

Current Status: Current surveillance is afflicted with several key challenges that make it difficult to track the prevalence of overdose events in settings where they commonly occur. First, there are limited data on the number of individuals revived outside of hospitals (such as by first responders or family members). Second, there is likely under-coding of overdose in hospital admissions data, and such coding may be imprecise as hospital personnel may not adhere to consistent protocol for coding overdoses. Third, medical examiners and coroners vary in the rigor and consistency of procedures they use to classify overdose fatalities. As a result, there is known under-coding bias in state data, making it difficult to ascertain consistent cross-state and national trends.²⁰³

6.3 USE FEDERAL FUNDING FOR INTERVENTIONS TO ADDRESS OPIOID-USE DISORDERS TO INCENTIVIZE INCLUSION OF OUTCOME DATA IN THOSE FUNDED PROGRAMS

In the current era, there are widespread efforts to address the opioid epidemic through a variety of federal programs including initiatives with PDMPs, Medicaid programs, and direct grants to states (e.g., the State Targeted Response grants under the 21st Century Cures Act). These programs should include detailed guidance for data collection of program outcomes and approaches to sharing data where feasible, as these standards would enable grantees to track how programs are being implemented in different settings.

Rationale: Promising interventions are in the field, and may be more effectively disseminated if there is a repository of evidence to share across states and localities. Population-based outcome data are lacking and needed to inform decisions about replication and scale-up of promising interventions.

Current Status: While there is some provision for evaluating current programs, the data are often not consistently collected or disseminated. Moreover, programs are sometimes implemented in a manner that makes rigorous evaluation difficult. For example, the State Targeted Response grants include some minimal guidance for state data collection, but are not likely to be feasible for impact evaluations in most states.

6.4 SUPPORT THE LINKAGE OF PUBLIC HEALTH, HEALTH CARE, AND CRIMINAL JUSTICE DATA RELATED TO THE OPIOID EPIDEMIC

The impact of the opioid epidemic reaches across multiple service systems, and important indicators of harm related to the epidemic are captured in hospitals, public health programs (e.g., HIV screening or naloxone distribution), and law enforcement data. Although there are clear privacy implications to sharing data across entities, there are also real benefits in terms of efforts to increase overdose prevention.

Rationale: Because there are multiple pathways into harmful opioid use, no single data system can fully capture markers of risk. Measuring outcomes across systems provides a more complete picture. It also provides the foundation for better evaluation of the effectiveness of coordinated approaches.

Current Status: There are limited instances of data sharing across different service systems. While analyses have been conducted linking, for example, law enforcement data with drug treatment data, these are usually relevant to relatively discrete populations and done retrospectively. Massachusetts, under the Chapter 55 legislation, has made important progress in developing a legal framework for linking data across multiple service systems.

7. TREATING OPIOID-USE DISORDERS

Pharmacotherapies for opioid addiction include agonist maintenance with methadone, partial-agonist maintenance with buprenorphine, and antagonist treatment with immediate-release or extended-release naltrexone. Multiple well-designed randomized controlled trials provide strong evidence that buprenorphine maintenance and methadone maintenance are safe, efficacious, and cost-effective treatments for opioid addiction.²⁰⁴ Both buprenorphine and methadone maintenance treatment are associated with reduced overdose risk, reduced risk of HIV infection, and improved maternal and fetal outcomes in pregnancy.^{205,206} However, when used short term, especially in detoxification regimens, evidence of enduring benefit is lacking.²⁰⁷

Psychosocial approaches to treating opioid addiction include therapeutic communities, cognitive-behavioral therapies and 12-step facilitation, either provided in professional treatment or by mutual support groups such as Narcotics Anonymous. While 12-step programs are valued by many addiction professionals, it has been difficult to determine which elements of these programs may be of greatest therapeutic value. Psychosocial interventions, like medication treatments, may occur in outpatient or inpatient settings. While some studies support improved effectiveness of combining psychosocial therapies with buprenorphine and methadone maintenance, abstinence-based psychosocial approaches that shun opioid agonist treatment are associated with poor outcomes^{208,209}

The ability to expand access to treatment with methadone is limited by a short supply of licensed programs in non-urban communities and requirements such as daily attendance. Unlike methadone maintenance, buprenorphine can be prescribed in an office-based setting. Unfortunately, there are barriers to buprenorphine treatment that include:

- **Federal limits on the number of patients a physician may treat with buprenorphine.** Physicians must apply to the Substance Abuse Mental Health Services Administration to provide buprenorphine treatment beyond the 30-patient limit for up to 100 patients with opioid dependency. Physicians who have prescribed buprenorphine to 100 patients for at least one year can now apply to increase their patient limits to 275 under new federal regulations.
- **Federal limits on nurse practitioners' and physician assistants' prescribing.** The Comprehensive Addiction and Recovery Act, signed into law on July 22, 2016, expanded buprenorphine prescribing privileges to nurse practitioners and physician assistants for five years (until October 1, 2021). Nurse practitioners and physician assistants must complete 24 hours of training for eligibility to obtain a DATA 2000 waiver and are limited to treating up to 30 patients.
- **Inadequate integration of buprenorphine into primary care treatment.** Physicians, nurse practitioners, physician assistants and other allied health care professionals receive little training in the recognition and treatment of opioid-use disorders.
- **Stigma against maintenance treatment for opioid addiction.** The misperception that maintenance medications substitute one drug for another is a commonly held view. These treatments have been underutilized because of misunderstandings about the drugs and their effectiveness and generally negative biases from the public, patients, criminal justice agencies, and providers.²¹⁰ Less than half of all licensed addiction treatment programs offer these medications, and less than half of the eligible patients in those programs receive them.²¹¹

TREATING OPIOID-USE DISORDERS

RECOMMENDATIONS FOR ACTION**7.1 PROVIDE A WAIVER FROM PATIENT CAPS FOR BUPRENORPHINE TREATMENT FOR CLINICS THAT IMPLEMENT EVIDENCE-BASED MODELS OF CARE**

Addiction specialist physicians are prohibited under federal law from treating more than 275 patients with buprenorphine.

Rationale: The current cap has no counterpart anywhere in medicine and has led to waiting lists for patients to receive treatment.

Current Status: Lifting these federally imposed caps is an action that the Comprehensive Addiction and Recovery Act (2016) delegated to the Secretary of the Department of Health and Human Services. Additional training of prescribers about opioid agonist treatment should be offered and treatment guidelines, such as the American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use,²¹² should be disseminated. Access to buprenorphine treatment across the country should be closely monitored by the federal government. This effort will involve collaboration with Substance Abuse and Mental Health Services Administration and the Drug Enforcement Agency.^{7.2}

7.2 REQUIRE ALL STATE-LICENSED ADDICTION TREATMENT PROGRAMS THAT ADMIT PATIENTS WITH OPIOID-USE DISORDERS TO PERMIT ACCESS TO BUPRENORPHINE OR METHADONE

State-licensed addiction treatment programs should not be permitted to admit patients with an opioid-use disorders unless they permit access to buprenorphine or methadone maintenance. So-called “abstinence only” program policies do not offer evidence-based treatment.

Rationale: Many state-licensed addiction treatment programs do not offer patients access to buprenorphine or methadone maintenance.

Current Status: In 2015, the White House Office of National Drug Control Policy announced that drug court programs will be ineligible to receive future federal funding if they prohibit receipt of buprenorphine and methadone. This effort will involve collaboration with SAMHSA, the Centers for Medicare and Medicaid Services, the White House Office of National Drug Control Policy and state drug and alcohol licensing agencies.

7.3 REQUIRE ALL FEDERALLY QUALIFIED HEALTH CENTERS TO OFFER BUPRENORPHINE

Federally Qualified Health Centers (FQHCs) are safety net providers that primarily provide services typically furnished in an outpatient clinic. They include community health centers, migrant health centers, homeless health centers, and public housing primary care centers as well as outpatient health programs or facilities operated by a tribal organization or by an urban Indian organization. In recent years, an increasing number of FQHCs have been offering buprenorphine²¹³ and they are one of the few providers that accept Medicaid for office-based buprenorphine treatment. Support and training for high quality treatment can be paired with the expectation that health centers offer this important therapy. Waivers for FQHCs that are structurally unable to meet this requirement should be available.

Rationale: Buprenorphine is an effective treatment for opioid addiction, yet access remains limited.

Current Status: The White House Commission on Combating Drug Addiction and the Opioid Crisis called on the Centers for Medicare and Medicaid Services to require all FQHCs to mandate that their staff physicians, physician assistants, and nurse practitioners possess waivers to prescribe buprenorphine.

7.4 ALLOCATE FEDERAL FUNDING TO BUILD TREATMENT CAPACITY IN COMMUNITIES WITH HIGH RATES OF OPIOID ADDICTION AND LIMITED ACCESS TO TREATMENT

To reduce opioid-related overdose deaths, access to buprenorphine and methadone maintenance must be improved. States and counties need federal assistance to develop and expand existing services so that low-threshold treatment is available to all individuals with opioid-use disorders seeking treatment, regardless of their ability to pay for it.

Rationale: Treatment services are disproportionately distributed across communities and do not always reflect need. Using federal resources to identify communities most in need of treatment services and to expand treatment capacity will help to address this disparity. *Current Status:* In 2017, \$28 million in funding provided by the 21st Century CURES Act was awarded to five grantees to increase access to opioid agonist treatment for opioid-use disorders.

TREATING OPIOID-USE DISORDERS

7.5 DEVELOP AND DISSEMINATE A PUBLIC EDUCATION CAMPAIGN ABOUT THE ROLE OF TREATMENT IN ADDRESSING OPIOID ADDICTION

Utilize information from the Department of Health and Human Services and the National Institute on Drug Abuse through the CDC and the White House Office of National Drug Control Policy to educate providers, patients and their families, health plans, state level law enforcement, and policy makers on the nature of opioid addiction as a chronic brain disease, noting that the strongest evidence supports use of maintenance medication with either methadone or buprenorphine. This campaign should also aim to reduce the stigma associated with effective treatment options. A major public education campaign on appropriate treatment that is comprehensive, evidence-based, and follows best practices in health communication is needed and should be evaluated.

Rationale: There is a lack of awareness about the effectiveness of opioid agonist treatment options among providers, patients and their families, health plans, law enforcement, and policy makers, and there is stigma against medication treatment. Both the lack of information and the stigma associated with opioid agonist treatment are barriers to greater use of effective treatment. Opioid agonist treatment is the standard of care for opioid addiction and it should be known as such among providers and the public.

Current Status: Federal health officials from the CDC, National Institutes of Health and the Substance Abuse and Mental Health Services Administration have made public statements supporting opioid agonist treatment. The latter two agencies have also issued materials for health care providers and the public on treatment with buprenorphine. Some health departments, most notably the New York City Department of Health and Mental Hygiene and the Maryland Department of Health, have sponsored efforts to raise awareness and improve access to treatment with buprenorphine and methadone.

7.6 EDUCATE PRESCRIBERS AND PHARMACISTS ABOUT HOW TO PREVENT, IDENTIFY, AND TREAT OPIOID ADDICTION

Develop, evaluate, and disseminate prescriber and pharmacist education to assist in better preventing, identifying, and treating opioid addiction. Training should include both information as well as direct skill development in assessment and treatment of opioid-use disorders. Develop, evaluate, and disseminate information about the standard of care for treatment of opioid addiction to providers who treat patients with opioid-use disorders.

Rationale: Prescribers and pharmacists receive little training on substance use disorders. With improved understanding of the etiology of opioid addiction and its treatment, they may be better able to prevent, recognize, and care for patients suffering from this condition.

Current Status: The American Society of Addiction Medicine and the American Academy of Addiction Psychiatry are currently involved in efforts to improve medical education about substance use disorders. A coordinated national effort to educate prescribers and pharmacists about opioid addiction is not yet underway.

7.7 ESTABLISH ACCESS TO OPIOID AGONIST TREATMENT WITH BUPRENORPHINE AND METHADONE MAINTENANCE IN JAILS AND PRISONS

Rationale: Many people with opioid-use disorders are incarcerated in jails and prisons, but are rarely offered treatment with buprenorphine or methadone. In contrast, use of extended-release naltrexone upon release from jail and prison is becoming more common despite limited evidence of its effectiveness. Opioid agonist treatment with buprenorphine and methadone is an effective intervention in these settings and can reduce incarceration and recidivism.^{214,215}

Current Status: Opioid agonist treatment is available at fewer than 40 of the more than 5,000 jails and prisons in the United States.²¹⁶ In many criminal justice settings, the only available medication is extended release naltrexone.

TREATING OPIOID-USE DISORDERS

7.8 INCENTIVIZE INITIATION OF BUPRENORPHINE IN THE EMERGENCY DEPARTMENT AND DURING HOSPITAL STAYS

Rationale: Opioid-use disorders is more prevalent in patients who present to emergency departments than in the general population.²¹⁷ Patients with opioid-use disorders are admitted to hospitals for treatment of opioid overdose, opioid withdrawal, medical problems associated with injection drug use, and other health conditions. Similar to hospital initiated treatment for chronic disorders such as hypertension and diabetes, patients who initiate buprenorphine in hospitals have better outcomes than patients referred for initiation of treatment as an outpatient.²¹⁸

Current Status: Few hospital emergency departments and medical inpatient units offer this standard of care, despite support from the U.S. Surgeon General.²¹⁹

8. IMPROVING NALOXONE ACCESS AND USE

Most evaluations of Overdose Education Naloxone Distribution programs (OEND) report on program implementation; training lay persons to recognize and respond to an overdose event, including the administration of naloxone; and provide information on the number of individuals trained, number of naloxone vials distributed and the number of overdose reversals reported by individuals who were trained (Kerensky 2017).

The settings for OEND evaluations have primarily been in large urban center needle and syringe exchange or harm reduction programs, methadone programs or other opioid-use disorders treatment programs, and have focused on people who inject heroin. Evaluations of programs in New York City, Massachusetts, Los Angeles, San Francisco, Chicago, Rhode Island, Pittsburgh, and Baltimore have been reported in the published literature.²²⁰⁻²²¹ Because the focus of the evaluations has been on the number of trained individuals and overdose reversals reported, it is not possible to describe the population-level impact of these individual programs. Data from a 2014 survey found that OEND programs in the U.S. had trained and provided naloxone to more than 150,000 individuals between 1996 and 2014, and reported more than 26,000 opioid overdose reversals during this time.²²² Additional evaluations have reported on changes in overdose recognition and response knowledge and/or behaviors as a result of OEND program training.²²³⁻¹⁶³ Taken together, these data demonstrate that people at high risk for opioid overdose and their friends or family members can successfully be trained to recognize and respond to an overdose, and appropriately administer naloxone in an overdose situation.

The literature examining the broader public health impact of OEND programs is growing. Two identified studies described the Project Lazarus program in North Carolina, which was created in 2008. One component of this program is the co-prescription of naloxone to people at risk for opioid overdose. An initial evaluation of Project Lazarus in Wilkes County, North Carolina, found significant declines in the unintentional drug overdose death rate from a peak of 46.6 deaths per 100,000 population in 2009 to 29.0 deaths per 100,000 in 2010 and 14.4 deaths per 100,000 in 2011.^{224,225} However, because Project Lazarus includes overdose prevention components unrelated to naloxone, it is difficult to determine the exact role naloxone played in the reduction of Wilkes County's unintentional drug overdose deaths.

Walley et al., provide an important evaluation examining changes in health outcomes as a result of OEND program implementation. They conducted an interrupted time-series analysis to evaluate the impact of Massachusetts' OEND program on opioid overdose deaths and non-fatal opioid overdose acute care hospital utilization rates from 2002 to 2009. They found that communities that implemented OEND programs during the study time had statistically significant reductions in opioid overdose death rates compared to communities that did not implement OEND programs. Acute care hospital utilizations did not differ between OEND program communities and those that did not implement one.¹³⁰

In recent years, there has been a push to increase naloxone prescribing in the pain management setting and to equip first responders with naloxone. Coffin et al., found among patients prescribed opioids for chronic pain that those who were prescribed naloxone had 47 percent fewer opioid emergency department visits per month in the six months after receiving naloxone and 63 percent fewer visits after one year compared to patients who did not receive naloxone.²²⁶ Rando et al., assessed the impact of a first responder naloxone program in Ohio and found that opioid overdose deaths declined after implementation of the program.²²⁷ There have also been efforts to increase access to naloxone through the use of "standing orders" that allow for an individual to fill a prescription for naloxone based on a pre-approved order from a licensed prescriber.²²⁸

Based on recent systematic analyses, the available evidence suggests that naloxone is a promising strategy with some evidence of effectiveness in reducing opioid overdose mortality rates.²²⁹ Limitations of the available studies include lack of randomization of distribution methods; lack of generalizability because the data are almost exclusively based on people who inject drugs, primarily heroin; self-reported outcomes; short-term follow-up; significant loss to follow-up; and lack of control over other events occurring simultaneously that could be responsible for effects.²³⁰

IMPROVING NALOXONE ACCESS AND USE

RECOMMENDATIONS FOR ACTION**8.1 PARTNER WITH PRODUCT DEVELOPERS TO DESIGN NALOXONE FORMULATIONS THAT ARE EASIER TO USE BY NON-MEDICAL PERSONNEL AND LESS COSTLY TO DELIVER**

Rationale: As the legal landscape changes to allow broader access to naloxone, different populations may prefer different delivery mechanisms for naloxone. Having multiple products that are easy for non-medical personnel to use would likely increase uptake and reduce costs. Price is consistently raised as a concern impacting the sustainability of various OEND programs, and recent reports indicate that the cost of the drug is increasing dramatically.^{231,232} Further, the emergence of highly potent illicitly made synthetic opioids such as fentanyl and carfentanil have raised concerns over the need for higher naloxone doses to successfully reverse overdoses – increasing concerns over costs and the effectiveness of current naloxone formulations.

Current Status: An auto-injector formulation of naloxone with audio guidance (Evzio) was approved by the FDA in April 2014. A nasal formulation (Narcan) was approved in 2015. Many formulations, however, remain financially inaccessible.

8.2 WORK WITH INSURERS AND OTHER THIRD-PARTY PAYERS TO ENSURE COVERAGE OF NALOXONE PRODUCTS

Cost remains a significant concern with regard to sustainability of naloxone programs.

Rationale: One approach to sustaining expanded access to naloxone is through coverage by third-party payers.

Current Status: Some states and localities have made progress in gaining coverage for certain naloxone products. However, this has not been accomplished in a systematic way.

8.3 WORK WITH COMMUNITY-BASED OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS TO IDENTIFY STABLE FUNDING SOURCES TO ENSURE PROGRAM SUSTAINABILITY

Rationale: Some community-based programs have little to no dedicated funding for the purchase and provision of naloxone. These programs provide critical access to naloxone among high-risk populations.

Current Status: The federal government now has multiple grant programs through both the U.S. Department of Health and Human Services and the Department of Justice to expand access to naloxone. However, it is not clear how these funds will impact community-based programs. Other community-based programs have worked with local and state agencies to develop a sustainable funding model and their experience could be informative to other programs across the country.

8.4 ENGAGE WITH THE SCIENTIFIC COMMUNITY TO ASSESS THE RESEARCH NEEDS RELATED TO NALOXONE DISTRIBUTION EVALUATIONS AND IDENTIFY HIGH PRIORITY FUTURE DIRECTIONS FOR NALOXONE-RELATED RESEARCH

Rationale: Naloxone is a promising strategy for reversing overdose and reducing overdose deaths. Rigorous, high-quality research is needed to explore the relative effectiveness of naloxone use in different settings, through different OEND mechanisms (including care and follow-up after overdose reversal events), and on prescription opioid (as opposed to heroin) overdose. With the entree of large scale providers, such as the Veterans Administration into the OEND space, and the expansion of pharmacy-based naloxone via standing orders, opportunities for more robust and definitive evaluations exist.

Current Status: There are several evaluations currently underway. However, available funding to evaluate the various types of programs being implemented is insufficient. The scientific community needs to further engage in a discussion on the various research approaches to evaluate naloxone programs being implemented in a variety of settings.

8.5. ENGAGE WITH THE HEALTH CARE PROFESSIONAL COMMUNITY TO ADVANCE CONSENSUS GUIDELINES ON THE CO-PRESCRIPTION OF NALOXONE

Rationale: There is no consensus on which patients should be co-prescribed or prescribed naloxone in general medical settings. Recent studies show a number of logistical and attitudinal barriers to naloxone co-prescription. However, at least one study demonstrated a positive effect on opioid-related emergency department visits associated with co-prescribing naloxone to patients treated with opioids for chronic pain.²³³

IMPROVING NALOXONE ACCESS AND USE

Current Status: Several medical societies have adopted resolutions supporting naloxone co-prescription to patients, and some health systems such as the Veterans Administration have begun implementing campaigns to increase naloxone co-prescription. The CDC, in their Guideline for Prescribing Opioids for Chronic Pain, recommends that clinicians incorporate strategies to mitigate risk into the management plans of patients receiving opioids, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present. However, to date, there is no consensus on the most appropriate patients for naloxone co-prescription.

8.6 ASSESS THE EFFECTS OF STATE LAWS EXPANDING NALOXONE ACCESS TO THE GENERAL PUBLIC

All 50 states and the District of Columbia have made progress in expanding naloxone access to the general public, such as through the use of standing orders from a licensed prescriber.²³⁴ These laws vary and there is a need to assess which types of laws are most effective in achieving beneficial outcomes on the public's health.

Rationale: Administration of naloxone by non-medical personnel has been shown to be both safe and effective for preventing overdose deaths.²³⁵ The current variation in state laws is ripe for evaluations that can provide guidance regarding the most effective policies.

Current Status: All 50 states and the District of Columbia have laws that facilitate naloxone access by non-medical personnel. These laws vary with in the scope of coverage and the circumstances under which they apply.

9. EXPANDING HARM REDUCTION STRATEGIES

Substance-use disorders, and those involving opioids, are increasingly understood as a chronic condition for which effective treatment exists. However, significant barriers to access involving limited investment and inadequate resources, misconceptions about treatment, and stigma limit the current impact of treatment on the opioid epidemic. In addition, treatment entry is not always feasible for people with opioid-use disorders. Harm reduction was borne out of the belief that harms associated with drug use can be reduced while people are actively engaged in drug use. Beginning in the Netherlands in the late 1980s,²³⁶ it took footing in the U.S. in light of the HIV epidemic among people who inject drugs, with advocacy for establishing needle and syringe service programs. In many ways, harm reduction is as much a social movement as guidance for a set of practical policies and programs focused on people who use drugs. In the context of the current opioid crisis, harm reduction schemes such as needle and syringe service programs and naloxone distribution programs are now considered legitimate public health responses and not surrounded by as much controversy as in the past. As some view harm reduction as a permissive attitude toward illicit drug use, some harm reduction approaches such as supervised consumption sites remain controversial as a viable or legitimate approach to addressing opioid-use disorders. Efforts to increase the recognition and use of evidence-based and promising harm reduction strategies are needed.

The Harm Reduction Coalition defines harm reduction as “a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use. Harm reduction is also a movement for social justice built on a belief in, and respect for, the rights of people who use drugs.”²³⁷ In the U.S., harm reduction approaches are often traced back to the early days of HIV, when sharing needles and syringes among people who inject drugs was identified as a risk factor in the spread of the disease. In order to prevent transmission of HIV and Hepatitis C, some medical, public health, and substance-use professionals sought interventions to minimize the disease risks associated with injecting drugs. This was part of a larger paradigm shift still underway to frame and address injection drug use as a medical issue.

The most prominent harm reduction scheme is that of needle and syringe service programs, where individuals can receive clean needles and syringes and other “works” (e.g., cottons, cookers) and dispose of used and potentially contaminated equipment. Over the past three decades, numerous evaluations of needle and syringe service programs demonstrate reductions in the transmission of HIV, Hepatitis C, and show increases in treatment seeking among people who inject drugs as well as other positive health outcomes.^{238,239,240} Providing access to equipment that is free of life-threatening viruses is a cornerstone of harm reduction and disease prevention efforts for people who inject drugs.

Efforts to provide supervised consumption sites in which sterile needles and syringes are available, and injecting practices can be monitored by medically trained staff have also demonstrated reductions in disease transmission and overdose rates, and increases in treatment uptake. Unlike needle and syringe service programs which have been in place in U.S. cities for decades, sanctioned supervised consumption sites have only existed in communities outside of the U.S., primarily throughout Europe where it is considered a component of a public health response to drug use. There are supervised consumption sites in Vancouver, British Columbia as well as Sydney, Australia. The majority of studies evaluating the impact of supervised consumption sites derive from Vancouver where the program was initiated as a pilot and there was a national legal battle for its continued existence. The overwhelming evidence shows that supervised consumption sites are associated with reductions in overdose,²⁴¹ HIV infections,²⁴² HCV transmission,²⁴³ unsafe injection practices, and fatal and non-fatal overdoses within the facility and in the surrounding area.^{244,245,246,247} A survey conducted in Boston, Massachusetts suggests that people who inject drugs, and those who are at high risk for overdose are likely to use supervised consumption sites.²⁴⁸

RECOMMENDATIONS FOR ACTION

9.1 ESTABLISH AND EVALUATE SUPERVISED CONSUMPTION SPACES

Establish supervised consumption spaces as a part of a comprehensive response to the opioid overdose epidemic, along with evidence collection and evaluation to understand their optimal design and impact. Planning should include medical professionals, people with lived experiences of drug use, case managers, and community-based organizations to ensure programs are designed comprehensively to meet the needs of people who use drugs. Such programs should provide comprehensive services, including injection supervision by medical professionals, sterile injection equipment, and naloxone as well as case management, treatment information and referral support, and primary care services.

Rationale: Supervised consumption spaces are an evidence-based strategy that has been employed outside of the U.S. to reduce opioid overdose, infectious disease transmission, and other injection-related health risks. Supervised consumption spaces also connect people who inject drugs with treatment services, and can decrease addiction rates.²⁴⁹ A recent review of the peer-

EXPANDING HARM REDUCTION STRATEGIES

reviewed literature concluded that supervised consumption spaces are associated with reductions in overdose deaths within and in the area surrounding supervised consumption spaces, reductions in injection drug use, and do not increase crime or drug use in the communities where they are located.²⁵⁰ However, there is insufficient evidence derived from the United States regarding the effects and potential unintended consequences of these spaces since such spaces are not sanctioned in the U.S. Thus, sanctioned programs in the United States, once introduced, should be evaluated.

Current Status: Sanctioned supervised consumption spaces have been in place in more than 100 cities in 10 countries since 1986 when the first site opened in Bern, Switzerland. None of these sites are in the U.S. However, one unsanctioned U.S. space is described in the literature.²⁵¹ Several U.S. states and localities are considering policies to establish supervised consumption spaces.

9.2 WORK WITH STATE AND LOCAL STAKEHOLDERS TO ESTABLISH AND SUPPORT NEEDLE AND SYRINGE SERVICE PROGRAMS

Updates to laws at the federal, state, and local levels allow for agencies and organizations in many communities to supply sterile needles and syringes to people who inject drugs, including opioids.²⁵² Such programs should follow best practices, which include distribution as opposed to any restricted exchange policies which are associated with increased rates of needle and syringe sharing and elevated HIV prevalence. Services are best provided in a comprehensive manner including referrals to drug treatment and other necessary services (e.g., housing, case management). People with lived experiences should be involved with designing and delivering services to enhance the relevancy of these programs.

Rationale: Providing sterile needles and syringes to people who inject drugs has been shown to reduce the spread of HIV, Hepatitis C, and increase uptake of drug treatment among people who inject drugs.^{253,254,255,256,257}

Current Status: A 2016 modification to federal law allows for federal funds to be used for programmatic support and services related to needle and syringe service programs, though not for purchasing the needles and syringes themselves.²⁵⁸ State and local governments and non-government programs can use this policy shift to expand the scope and reach of existing harm reduction efforts. State and local laws vary with regard to the legality of distributing needles, syringes, and other drug-use paraphernalia.²⁵⁹

9.3 EVALUATE AND DISSEMINATE THE USE OF TEST KITS FOR FENTANYL IN OPIOIDS

Test kits provide people with information about the content of their drugs.

Rationale: Recent experience has shown the deadly impact that the evolving synthetic opioid market can have. More potent opioids, such as fentanyl, are increasingly common in the U.S., and are often illicitly manufactured to resemble less-potent opioids.²⁶⁰ Many of those dying from exposure to high potency preparations may have been unaware of the risk.^{261,262} Providing people with the means to test their drug supply for adulterants may affect their decisions about which drugs to use or how to use them.

Current Status: Harm reduction organizations in some U.S. communities are using fentanyl test strips as a low threshold method of testing the presence or absence of fentanyl in street-purchased drugs. We are aware of research underway to test the validity and utility of these test strips, and the impact of their use on behavior and overdose. At the time of this writing, there were no peer-reviewed publications of reporting the results of such research.

10. COMBATING STIGMA

Stigma is an attitude, behavior, or condition that is socially discrediting.²⁶³ Both cause and controllability affect stigma. Survey research documents indicators of stigma toward people with opioid-use disorders within both the general public²⁶⁴ and health care providers.²⁶⁵ Such attitudes have implications for how interventions to address opioid-use disorders are conceptualized and supported. In studies using varied descriptions of the same person and scenario, framing opioid addiction as the result of irresponsible behavior for which the person with the disorder is to blame results in less supportive reactions to individuals with the associated disorders relative to when addiction is described as the result of environmental and biological influences.^{266,267,268} Similarly, when messages emphasize structural barriers to treatment and highlight success stories as opposed to featuring untreated addiction, people are more likely to express support for policies expanding treatment.^{269,270,271}

Language to reduce stigma is also important in how people are described. Separating the person from their disorder by avoiding references to people as “substance abusers” and “addicts” and instead describing an individual as “having an opioid-use disorders” can promote a medical frame and emphasize the disease qualities and treatment options available.²⁷² This change in language is consistent with a trend in appreciating the importance of language in the clinical context and with the more general practice of referring to people as having a particular condition, as opposed to being defined by their condition (e.g., a person has cancer, but is not cancer). McGinty et al provide a detailed review of the literature on these topics that reflects the findings from a consensus process of national experts and includes recommendations for research.²⁷³

RECOMMENDATIONS FOR ACTION

10.1 UPDATE EMPLOYER HUMAN RESOURCES AND BENEFITS LANGUAGE TO AVOID STIGMATIZING LANGUAGE AND INCLUDE EVIDENCE ABOUT THE EFFECTIVENESS OF TREATMENT FOR OPIOID-USE DISORDERS

Public and private sector employers have human resource policies and benefits packages that include information about substance use disorders and the treatment options available through insurance plans offered. Such materials should reflect current understanding of how best to communicate about opioid-use disorders to avoid stigmatizing language and encourage treatment.

Rationale: The workplace is an important source of information about health care, and can provide information about the medical nature of opioid-use disorders and the effectiveness of treatment in a way that is consistent with the evidence about constructive, non-stigmatizing language. It is also a potential source of support for employees who are grappling with opioid addiction, contemplating treatment, in treatment, or in recovery. Employers have an opportunity to reframe the response to opioid-use disorders within the workplace by using language that is supportive rather than stigmatizing, disseminating information about the effectiveness of treatment and creating an environment where supportive, constructive dialogue can occur.

Current Status: Workplaces offering supported employment and services for people who are in recovery or seeking to treatment for opioid-use disorders provide examples of how to address stigma in the workplace.

10.2 AVOID STIGMATIZING LANGUAGE AND INCLUDE INFORMATION ABOUT THE EFFECTIVENESS OF TREATMENT AND THE STRUCTURAL BARRIERS THAT EXIST TO TREATMENT WHEN COMMUNICATING WITH THE PUBLIC ABOUT OPIOID-USE DISORDERS

Media coverage of the opioid epidemic, and public and private sector initiatives to educate and intervene should avoid stigmatizing language and apply the available evidence when communicating with the public about opioid-use disorders.

Rationale: Messages about the effects of opioid-use disorders on individuals, families, and communities are ubiquitous, as are educational campaigns and interventions designed to reverse the trend. Because how the opioid epidemic is discussed and how people with opioid-use disorders are portrayed affects support for effective interventions, assuring that the language and frames embedded in media reports and interventions are consistent with the available evidence is important to maximizing these efforts.

Current Status: Several professional organizations and groups have written statements and recommendations about what language to use and what language to avoid, including the recent 2017 Associated Press Stylebook.²⁷⁴ Reports from professional associations and government-led initiatives provide evidence-based guidance for use by the media, professionals, and agencies and organizations that are active in this work.^{275,276,277}

COMBATING STIGMA

10.3 EDUCATE HEALTH CARE PROVIDERS ABOUT THE BENEFITS ASSOCIATED WITH DESTIGMATIZING LANGUAGE

Rationale: Health care providers are key stakeholders in addressing opioid-use disorders. Research documenting the presence of stigma and the use of stigmatizing language among health care providers demonstrates a need for greater awareness about the counter-productive impacts of stigmatizing language, and is an opportunity for intervention.

Current Status: Educational resources are available through several agencies, organizations, and professional associations.^{278,279,280}

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Expert Witness Report of G. Caleb Alexander, MD, MS

Appendix B – Curriculum Vitae

May 2021

CURRICULUM VITAE
G. Caleb Alexander, MD, MS

PERSONAL DATA

Business Address

Johns Hopkins School of Public Health
Center for Drug Safety and Effectiveness
Department of Epidemiology
615 N. Wolfe Street W6035
Baltimore, MD 21205
Phone: 410 955 8168
Fax: 410 955 0863
Email: galexand@jhsphe.edu

Clinical Address

Johns Hopkins at Green Spring Station
10753 Falls Road Suite 325
Lutherville, MD 21093
Clinic Phone: 410 583 2926
Clinic Fax: 410 583 2883

EDUCATION AND TRAINING

1988-1990	Candidate for BA, Oberlin College
1991-1993	University of Pennsylvania, BA (Philosophy)
1994-1998	Case Western Reserve University, MD
1998-1999	Intern, Internal Medicine, University of Pennsylvania
1999-2001	Resident, Internal Medicine, University of Pennsylvania
2001-2003	Robert Wood Johnson Clinical Scholar, University of Chicago
2002-2003	University of Chicago, Department of Health Studies, MS

Medical Licensure

Maryland Physician and Controlled Substance License, through 9/30/20
Drug Enforcement Agency Controlled Substance Licensure, through 6/30/21

Medical Board Certification

American Board of Internal Medicine, through 12/31/22

PROFESSIONAL EXPERIENCE

2001-2003	Off-tour Attending Physician, Veterans Affairs Hospital, Hines, Illinois
2003-2005	Instructor, Division of General Medicine, University of Chicago
2003-2006	Affiliate Faculty, Robert Wood Johnson Clinical Scholars Program
2003-2012	Affiliate Faculty, MacLean Center for Clinical Medical Ethics
2005-	Adjunct Research Associate, Department of Pharmacy Practice, University of Illinois at Chicago School of Pharmacy
2005-2011	Assistant Professor, Division of General Medicine, University of Chicago

2007-2012	Affiliate Faculty, Center for Interdisciplinary Health Disparities Research (CIHDR), University of Chicago
2011-2012	Associate Professor, Division of General Medicine, University of Chicago
2012-	Founding Co-Director, Johns Hopkins Center for Drug Safety and Effectiveness Hopkins University
2012-2018	Associate Professor of Epidemiology and Medicine, Johns Hopkins Bloomberg School of Public Health
2014-	Affiliate Faculty, Center for Health Services and Outcomes Research (CHSOR), Johns
2018-	Professor of Epidemiology and Medicine, Johns Hopkins Bloomberg School of Public Health

PROFESSIONAL ACTIVITIES

Society Membership and Leadership

1998-2001	Philadelphia County Medical Society
1998-2009	American Medical Association
1998-	Physicians for Social Responsibility
1998-	Alpha Omega Alpha Medical Honors Society
2000-	Society for General Internal Medicine
2000-	American College of Physicians
2003-2009	American Society of Bioethics and Humanities
2006-2007	Chair, Program Committee, RWJ Faculty Scholars National Meeting
2006	Member, Program Committee, RWJ Faculty Scholars National Meeting
2007-	International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
2008	Selection Committee, Midcareer Research Mentorship Award, SGIM
2009-	International Society for Pharmacoepidemiology (ISPE)

Non-Commercial Advisory Boards

2000-2003	Transplant Task Force, End Stage Renal Disease Renal Network #9/#10
2005	American Society of Bioethics and Humanities President's Advisory Committee on Ethics Standards
2007-2011	Cost of Cancer Care Task Force, American Society of Clinical Oncology
2008-2016	Charter Member, IMS Health Services Research Network
2010-2014	FDA, Drug Safety and Risk Management Advisory Committees, Ad Hoc Member <ul style="list-style-type: none"> • October 2010 Cardiovascular and Renal Committee (Darbapoeitin) • October 2012 Endocrinologic and Metabolic Committee (lomitapide/mipomersen) • July 2013 Arthritis Committee (Criteria for axial spondyloarthritis) • November 2013 Peripheral & Central Nervous System Committee (Alemtuzumab) • May 2014 Public Meeting (Post Marketing Requirements for Opioid Analgesics) • July 2015 Bone, Reproductive and Urologic Drugs Committee (Flibanserin) • December 2015 Pulmonary & Allergy Drugs Committee (Cough Syrup/Codeine) • October 2016 Bone, Reproductive and Urologic Drugs Committee (desmopressin) • November 2017 Psychopharmacologic Drugs Advisory Committee (buprenorphine)
2014-2019	Chairman, FDA Peripheral and Central Nervous System Drugs Advisory Committee <ul style="list-style-type: none"> • November 2015 Peripheral & Central Nervous System Committee (Drisapersen) • April 2016 Peripheral & Central Nervous System Committee (Eterplirsen) • April 2018 Peripheral & Central Nervous System Committee (Cannabidiol)
2020-	Member, FDA Peripheral and Central Nervous System Drugs Advisory Committee <ul style="list-style-type: none"> • November 2020 Peripheral & Central Nervous System Committee (Aducanumab)

2015-2018	Center of Excellence for Comparative Effectiveness, University of Illinois at Chicago
2015-2017	Legal Science, LLC, contract through National Institutes of Drug Abuse to develop Prescription Drug Abuse Policy System
2016-	Scientific Advisory Board, Media Policy Center, Santa Monica, California
2016	Facilitator, Prioritizing Comparative Effectiveness Research Questions for Preventing Opioid Misuse in the Management of Pain: A Stakeholder Workshop (PCORI)
2020	U.S. Department of Health and Human Services, National Center for Health Statistics (NCHS), National Ambulatory Medical Care Survey (NAMCS) Workgroup
2020	Member, FDA Peripheral and Central Nervous System Drugs Advisory Committee
2020	National Academies of Science, Engineering and Medicine (NASEM). Equitable Distribution of a COVID-19 Vaccine. Reviewer.
2020-	Scientific Advisory Board. Spreading the Word: Training Journalists and Researchers to Communicate PCORI Comparative Effectiveness Research Findings.

Commercial Advisory Boards

2007-2018	IQVIA Institute for Healthcare Informatics
2014-2016	PainNavigator, LLC, Minneapolis, Minnesota
2015-2019	Delta Faucet Company, Indianapolis, Indiana
2016-2018	MesaRx Innovations, New York, New York
2017-	OptumRX National P&T Committee

Other Commercialization Activity

2017-	Co-Founder, Monument Analytics, A Health Care Consultancy
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Testimony and Briefings (Non-Litigation)

2012	Food and Drug Administration (Drug Labeling for Prescription Opioids)
2015	U.S. Senate Veterans' Affairs Committee (Prescription Opioids)
2016	Centers for Disease Control and Prevention (Prescription Opioids)
2016	Committee on Health and Government Operations, Maryland House of Delegates (Prescription Drug Monitoring Programs)
2016	Food and Drug Administration (Prescription Opioids)
2016	National Academy of Sciences, Institute of Medicine (Regulation of Opioids)
2017	Senate Finance Committee, Maryland House of Delegates (Prescription Drug Pricing)
2017	U.S. House of Representatives, Congressional Oversight Committee (Opioid Epidemic)
2018	Briefing for U.S. Senate Staff Hosted by Senator Ben Cardin (Opioid Epidemic)
2018	National Academy of Science, Engineering and Medicine (FDA Opioid Regulation)
2019	Maryland House of Delegates (Prescription Drug Monitoring Program)
2019	National Academy of Science, Engineering and Medicine (Non-pharmacologic pain management)

Other Testimony (Litigation)

- Expert Report in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804, in the U.S. District Court for the Northern District of Ohio (March 25, 2019, supplemented April 3, 2019, updated April 17, 2019 and October 8, 2019).
- Deposition Testimony in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804, in the U.S. District Court for the Northern District of Ohio (April 26, 2019).
- Expert Report in *State of Washington v. Purdue Pharma L.P. et al.*, Case No. 17-2-25505-0 SEA, in the Superior Court of Washington for King County (July 8, 2019).
- Disclosed as an expert witness in *State of Montana v. Purdue Pharma L.P. et al.*, Case No. 1:17-md-02804, in the Montana First Judicial District Court in Lewis & Clark County (August 1, 2019).

EDITORIAL ACTIVITIES

Peer Review Activities

Ad hoc reviewer – Journals

American Journal of Kidney Diseases	Health Services Research
American Journal of Managed Care	Hypertension
American Journal of Medicine	International Journal of Quality Improvement
American Journal of Preventive Medicine	JAMA
American Journal of Public Health	Journal of American College Health
Annals of Internal Medicine	Journal of the American Pharmacists Association
Archives of Internal Medicine	Journal of the American Society of Nephrology
BioMed Central (BMC) Gastroenterology	Journal of Clinical Ethics
BioMed Central (BMC) Infectious Diseases	Journal of General Internal Medicine
British Journal of Cancer	Journal of Rural Health
British Medical Journal	Medical Care
Canadian Medical Association Journal	Medical Decision Making
Clinical Therapeutics	Milbank Quarterly
CNS Drugs	New England Journal of Medicine
Disease Management and Health Outcomes	PharmacoEconomics
Drugs	Pharmacoepidemiology and Drug Safety
Health Affairs	Social Science and Medicine

Editorial Board Memberships

2007-2010	Medical Decision Making, Deputy Editor
2008-2012	Journal of General Internal Medicine, Deputy Editor
2008-2010	Society of General Internal Medicine Forum, Associate Editor
2010-2011	BMC Health Services Research, Associate Editor
2012-2014	Journal of the American Pharmacists Association (JAPhA), Editorial Board
2012-2014	Journal of General Internal Medicine, Editorial Board
2012-	Medical Care, Deputy Editor
2013-	Drug Safety, Editorial Board
2014-	Drugs – Real World Outcomes, Editorial Board

Grant Reviews

1. The Netherlands Organization for Health Research and Development (ZonMw), The Ministry of Health, Welfare, and Sport, The Hague, The Netherlands (2007)
2. The University of Chicago Program for Pharmaceutical Policy (2007-2010)
3. University of Chicago/University of Illinois at Chicago CDC Center for Health Promotion Economics (2007)
4. The University of Chicago Diabetes Research and Training Center (2008).
5. Agency for Healthcare Research and Quality, Special Emphasis Panel (R18), “Optimizing Prevention and Healthcare Management for the Complex Patient.” March 2008.
6. RFA 09-003. NIH Challenge Grants in Health and Science Research (RC21). April 2009.

7. National Institute of Aging Special Emphasis Panel (PO1). Medical Professionalism and Healthcare Grants. November 2009.
8. Agency for Healthcare Research and Quality Special Emphasis Panel (R18). Comparative Effectiveness Delivery System Demonstration Grants. July 2010.
9. Agency for Healthcare Research and Quality. Centers for Education and Research in Therapeutics (CERT) (U-19) Special Emphasis Panel. July 2011.
10. Swiss National Science Foundation. Drug Lag in Switzerland: Does it Exist and Why? June 2012.
11. Dutch Ministry of Health Grant Review. Optimizing the use of Over-the-Counter Medicines. October 2012.
12. Qatar National Research Fund Reviewer. November 2012.
13. Veterans Health Affairs Health Services Research and Development (HSR&D) Center of Innovation Review. February 2012.
14. Ad hoc reviewer. Agency for Healthcare Research and Quality. Health Care Research Training (HCRT) Study Section. January 2014 – July 2015.
15. Ad hoc reviewer. Canadian Institutes of Health Research (CIHR). Review Committee for the Drug Safety and Effectiveness Network (DSEN) and the Strategy for Patient-Oriented Research (SPOR) Catalyst Grant: Methods in Post-Market Drug Safety and Effectiveness Research. January 2015.
16. Study section member. Agency for Healthcare Research and Quality. Health Care Research Training (HCRT) Study Section. August 2015 – July 2018.
17. Chairman. Patient Centered Outcomes Research Institute. Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain Merit Review. May 2016.
18. Chairman. Patient Centered Outcomes Research Institute. Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain Merit Review. May 2017.
19. Chairman. Patient Centered Outcomes Research Institute. Assessment of Prevention, Diagnosis, and Treatment Options (APDTO) Program. August 2017.
20. Ad hoc reviewer. Johns Hopkins Center for Injury Research and Policy. June 2020.
21. Ad hoc reviewer. National Institute on Drug Abuse Special Emphasis Panel. Pediatric Formulations and Drug Delivery Systems and Psychoactive Surveillance. August 2020.
22. Technical Expert Panelist/Key Informant. Integrated Pain Management Programs and Multidisciplinary, Multi-modal Treatment Models. Agency for Healthcare Research and Quality. April 2021.

HONORS AND AWARDS

Honors

1993	Cum Laude, University of Pennsylvania
1997	Alpha Omega Alpha, Case Western Reserve University
2003-2005	John A. Oremus Memorial Scholar (\$40,000 Research Stipend), MacLean Center for Medical Ethics, University of Chicago
2006	Top 5% of reviewers, Medical Care (also received annually through 2011)
2007	Top 10% of reviewers, Ann Intern Med (also received 2008, 2009, 2014)
2011	Elected Fellow of the American College of Physicians (FACP)
2011	Top Reviewers, Pharmacoepidemiology and Drug Safety (annually through 2014)

Awards

2001	Edward W. Holmes Resident Research Award, University of Pennsylvania
2006-2009	Robert Wood Johnson Foundation Faculty Scholar Career Development Award
2007	Research Finalist, International Society for Pharmacoeconomics and Outcomes Research, Annual Meeting
2008	Outstanding Physician Scientist Award, Central Society for Clinical Research
2008	Career development award (\$10,000 Research Stipend), Central Society for Clinical Research
2008	Department of Medicine Research Award (awarded to trainee for mentored research; also received by mentored trainees in 2009 and 2010)
2009	Pritzker School of Medicine Sigma Xi Award for Impact on Science (awarded to trainee for mentored research)
2017	American Society of Health-System Pharmacy, Drug Therapy Research Award (awarded to trainee for mentored research and cv publication #144)
2020	Robert C. Witt Award, Best Article in Journal of Risk and Insurance (Publication #197)

PUBLICATIONS

Peer Reviewed Journal Articles (names of trainees are underlined>)

1. Szele F, **Alexander GC**, Chesselet MF. "Expression of molecules associated with neuronal plasticity in the striatum after aspiration versus thermocoagulatory lesions in the adult cortex in adult rats." Journal of Neuroscience. 1995;15:4429-4448. PMID: 7790918
2. **Alexander GC**, Fera B, Ellis R. "From the students: learning continuous improvement by doing it." Joint Commission Journal on Quality Improvement. 1996;22:198-205. PMID: 8664952
3. **Alexander GC**, Sehgal AR. Dialysis patient assessments of the quality of medical care provided by generalists, nephrologists and other specialists. American Journal of Kidney Disease. 1998;32:284-289. PMID: 9708614
4. **Alexander GC**, Sehgal AR. Barriers to cadaveric renal transplantation among blacks, women, and the poor. JAMA. 1998;280:1148-1152. PMID: 9777814
 Editorial: Milford EL. Organ transplantation--barriers, outcomes, and evolving policies. JAMA. 1998;280:1184-1185. PMID: 9777820

5. Lewin L, Agneberg B, **Alexander GC**. A course in end-of-life care for third year medical students. *Academic Medicine*. 2000;57:519-520. PMID: 10824792
6. **Alexander GC**, Sehgal AR. Why hemodialysis patients fail to complete the transplant process. *American Journal of Kidney Disease*. 2001;37:321-328. PMID: 11157373

Editorial: Chertow GM, Zenios SA. Gridlock on the road to kidney transplantation. *American Journal of Kidney Disease*. 2001;37:435-437. PMID: 11157389
7. Werner RM, **Alexander GC**, Fagerlin A, Ubel PA. The "hassle factor": How physicians respond when third party payers decline reimbursement for important health care services. *Archives of Internal Medicine*. 2002;162:1134-1139. PMID: 12020183
8. **Alexander GC**, Sehgal AS. Variation in access to kidney transplantation across dialysis facilities: using process of care measures for quality improvement. *American Journal of Kidney Disease*. 2002;40:824-831. PMID: 12324919

Editorial: Powe NR, Boulware LE. The uneven distribution of kidney transplants: getting at the root causes and improving care. *American Journal of Kidney Disease*. 2002;40:861-863. PMID: 12324926
9. **Alexander GC**, Werner RM, Fagerlin A, Ubel PA. Public support for physician deception of insurance companies. *Annals of Internal Medicine*. 2003;138:472-475. PMID: 12639080
10. **Alexander GC**, Wynia MK. Ready and willing? Physicians' sense of preparedness for bioterrorism. *Health Affairs*. September/October 2003;22:189-197. PMID: 14515895
11. **Alexander GC**, Casalino LP, Meltzer DO. Patient-physician communication about out-of-pocket costs. *JAMA*. 2003;290:953-958. PMID: 12928475
12. **Alexander GC**, Werner RM, Ubel PA. The costs of denying scarcity. *Archives of Internal Medicine*. 2004;164:593-596. PMID: 15037486
13. **Alexander GC**, Casalino LP, Tseng CW, McFadden D, Meltzer DO. Barriers to patient-physician communication about out-of-pocket costs. *Journal of General Internal Medicine*. 2004;19:856-860. PMCID: PMC1492500
14. **Alexander GC**, Tseng CW. Strategies to identify and assist patients burdened by out-of-pocket prescription costs. *Cleveland Clinic Journal of Medicine*. 2004;71:433-437. PMID: 15195778
15. Werner RM, **Alexander GC**, Fagerlin A, Ubel PA. Lying to insurance companies: the desire to deceive among physicians and the public. *American Journal of Bioethics*. 2004;4:1-7. PMID: 16192208
16. Dai C, Stafford RS, **Alexander GC**. National trends in Cox-2 inhibitor use since market release: non-selective diffusion of a selectively cost-effective innovation. *Archives of Internal Medicine*. 2005;165:171-177. PMID 15668363

Editorial: Solomon DH, Avorn J. Coxibs, science, and the public trust. *Archives of Internal Medicine*. 2005;165:158-160. PMID: 15668360
17. **Alexander GC**, Casalino LP, Metlzer DO. Physician strategies to reduce patients' out-of-pocket prescription costs. *Archives of Internal Medicine*. 2005;165:633-636. PMID: 15795338

18. Buss MK, **Alexander GC**, Switzer GE, Arnold RM. Assessing competence of residents to discuss end-of-life issues with patients. *Journal of Palliative Medicine*. 2005;8:363-371. PMID: 15890047
19. Lang P, Schwarze M, **Alexander GC**. New technologies meeting old professional boundaries: the emergence of carotid artery stenting. *Journal of the American College of Surgery*. 2005;200:854-860. PMID: 15922195
20. **Alexander GC**, Mohajir N, Meltzer DO. Consumers' perceptions about risk of and access to nonprescription medications. *J Am Pharm Assoc*. 2005;45:363-70. PMID: 15991758
21. Wang YR, **Alexander GC**, Meltzer DO. Lack of effect of guideline changes on LDL cholesterol reporting and control for diabetes visits in the U.S., 1995-2004. *Diabetes Care*. 2005;28:2942-4. PMID: 16306559
22. **Alexander GC**, Kurlander J, Wynia MK. Physicians in retainer ("concierge") practice: a national survey of physician, patient, and practice characteristics. *Journal of General Internal Medicine*. 2005;20:1079-83. PMCID: PMC1490281
23. **Alexander GC**, Lantos J. The doctor-patient relationship in the post-managed care era. *American Journal of Bioethics*. 2006;6:29-32. PMID: 16423784
24. Wang YR, **Alexander GC**, Meltzer DO. Screening and use of cholesterol-lowering drug therapy for primary and secondary prevention of coronary heart disease, 1999 and 2003. *Managed Care Interface*. 2006;19:25-30. PMID: 16453992
25. Piette J, Heisler M, Horne R, **Alexander GC**. A conceptually-based approach to understanding chronically-ill patients' responses to medication cost pressures. *Social science and medicine*. 2006;62:846-857. PMID: 16095789
26. Holmes HM, Cox-Hayley DM, **Alexander GC**, Sachs GA. Reconsidering medication appropriateness for patients late in life. *Archives of Internal Medicine*. 2006;166:605-609. PMID: 16567597
27. Schwarze ML, Sayla MA, **Alexander GC**. Exploring patient preferences for infrainguinal bypass surgery. *Journal of the American College of Surgery*. 2006;202:445-452. PMID: 16500249
28. **Alexander GC**, Delisser HM, Hansen-Flaschen J, Lantos J. Shoring up professionalism: building upon disagreements between house officers and attending physicians. *Canadian Family Physician*. 2006;52:286-287. PMCID: PMC1479701
29. **Alexander GC**, Sayla MA, Holmes HM, Sachs GA. Prioritizing and stopping prescription medicines. *Canadian Medical Association Journal*. 2006;174:1083-1084. PMCID: PMC1421477
30. **Alexander GC**, Hall M, Lantos J. Rethinking professional ethics in the cost-sharing era. *American Journal of Bioethics*. 2006;6:W17-W22. PMID: 16885085
31. Federman AD, **Alexander GC**, Shrank WH. Simplifying the Medicare Prescription Drug Benefit for physicians and patients. *Mayo Clinic Proceedings*. 2006;81:1217-1221. PMID: 16970218

32. Quinn MT, **Alexander GC**, Hollingsworth D, O'Connor KG, Meltzer DO, for the Corporate Contributions for Life Consortium. Design and evaluation of a workplace intervention to promote organ donation. *Progress in Transplantation*. 2006;16:253-259. PMID: 17007162
33. Colker TR, Casalino LP, **Alexander GC**, Lantos J. Should our well-child care system be redesigned? A national survey of pediatricians. *Pediatrics*. 2006;118:1852-1857. PMID: 17079554
34. **Alexander GC**, Larkin G, Wynia MK. Preparedness for bioterror and competing public health priorities: a national survey of primary care and emergency physicians. *Academic Emergency Medicine*. 2006;13:1238-1241. PMID: 16614456
35. Wang YR, **Alexander GC**, Stafford RS. Outpatient treatment and control of hypertension in Western Europe and the United States. *Archives of Internal Medicine*. 2007;167:141-147. PMID: 17242314
36. Schwarze ML, Sayla MA, **Alexander GC**. A comparison of patient and physician beliefs about infrainguinal bypass surgery: what role should surgical optimism play? *Surgery*. 2007;141:239-244. PMID: 17263981
37. Casalino LP, **Alexander GC**, Jin L, Konetzka T. General internists' views on pay-for-performance and public reporting of quality scores: a national survey. *Health Affairs*. 2007;26:492-499. PMID: 1733967
38. Pham HH, **Alexander GC**, O'Malley AS. Physician consideration of patients' out-of-pocket costs in making common clinical decisions. *Archives of Internal Medicine*. 2007;167:663-668. PMID: 17420424
39. Torke A, **Alexander GC**, Lantos J, Siegler M. The doctor-surrogate relationship. *Archives of Internal Medicine*. 2007;167:1117-1121. PMID: 17563018
40. Kuwabara SA, Van Voorhees BW, Gollan JK, **Alexander GC**. A qualitative exploration of depression in emerging adulthood. *General hospital psychiatry*. 2007;29:317-324. PMCID: PMC2769013
41. Tseng CW, Brook RH, Keeler E, Steers WN, **Alexander GC**, Waitzfelder BE, Mangione CM. Elderly patients' preferences and experiences with providers in managing their drug costs. *Journal of the American Geriatrics Society*. 2007;55:1974-1980. PMID: 1794489
42. Phongsak SK, Wynia MK, Gadon M, **Alexander GC**. Original Communication: A Qualitative Study of Physicians' Engagement in Reducing Health Care Disparities. *Journal of the National Medical Association*. 2007;99:1315-1322. PMCID: PMC2575935
43. Yin W, Basu A, Zhang J, Rabbani A, Meltzer DO, **Alexander GC**. Impact of the Medicare Part D Prescription Drug Benefit on drug utilization and out-of-pocket expenditures. *Annals of Internal Medicine*. 2008;148:169-177. PMID: 18180465

Editorial: Stuart B. Where are the Medicare Part D claims data? *Annals of Internal Medicine*. 2008;148:1-2. PMID: 18180463
44. **Alexander GC**, Zhang J, Basu A. Characteristics of patients receiving pharmaceutical samples and association between sample receipt and out-of-pocket prescription costs. *Medical Care*. 2008;46:394-402. PMID 18362819

45. **Alexander GC**, Lin S, Sayla M, Wynia MK, Writing for the Data Committee of the Commission to End Health Care Disparities. Development of a measure of physician engagement in addressing racial and ethnic health care disparities. *Health Services Research*. 2008;43(2):773-84. PMID: PMC2442375
46. Rabbani A, **Alexander GC**. Out-of-pocket and total costs of fixed dose combination antihypertensives and their components. *American Journal of Hypertension*. 2008;21(5):509-13. PMID: 18437141
Editorial: Arredondo A. Out-of-pocket costs to users: medicine options for hypertension. *American Journal of Hypertension*. 2008;21:492–492. PMID: 18437138
47. Torke A, Simmerling M, Siegler M, Kaya D, **Alexander GC**. Rethinking the ethical framework for surrogate decision-making: a qualitative study of physicians. *Journal of Clinical Ethics*. 2008;19:110-119. PMID: 18767471
48. Torke A, **Alexander GC**, Lantos J. Substituted judgment: the limitations of autonomy in surrogate decision-making. *Journal of General Internal Medicine*. 2008;23:1514-1517. PMID: PMC2518005
49. Zhang J, Yin W, Sun S, **Alexander GC**. Impact of the Medicare Prescription Drug Benefit on the use of generic drugs. *Journal of General Internal Medicine*. 2008;23:1673-1678. PMID: PMC2533371
50. **Alexander GC**, Sehgal NL, Moloney RM, Stafford RS. National trends in treatment for Type 2 diabetes mellitus, 1994-2007. *Archives of Internal Medicine*. 2008;168:2088-2094. PMID: PMC2868588
51. Epstein AJ, Rathore SR, **Alexander GC**, Ketcham J. Physicians' Views on Access to Prescription Drugs under Medicare Part D. *American Journal of Managed Care*. 2008;14:SP5-SP13. PMID: 18991482
52. Peek ME, Tang H, **Alexander GC**, Chin MH. National prevalence of lifestyle counseling or referral among African Americans with diabetes. *Journal of General Internal Medicine*. 2008;23:1858-1864. PMID: PMC2585691
53. Walton SM, Schumock GT, Lee KV, **Alexander GC**, Meltzer D, Stafford RS. Prioritizing medications for policy and research initiatives examining off-label prescribing. *Pharmacotherapy*. 2008;28:1443-1452. PMID: 19025425
54. Qato DM, **Alexander GC**, Conti RM, Johnson M, Schumm P, Lindau ST. Use of prescription and over-the-counter medicines and dietary supplements among older adults in the United States: findings from a population-based study. *JAMA*. 2008;300:2867-2878. PMID: PMC2702513
55. Schwarze ML, Sayla MA, **Alexander GC**. Do patients with poor outcomes regret having had infrainguinal bypass surgery? *Journal of Surgical Research*. 2009;151:6-9. PMID: 17644108
56. **Alexander GC**, Stafford RS. Does comparative effectiveness have a comparative edge? *JAMA*. 2009;301:2488-2490. PMID 19531789
57. Rabbani A, **Alexander GC**. Determinants of health care use among children: evidence from rural Bangladesh. *Journal of Biosocial Science*. 2009;41:645-660. PMID: 19531272
58. Chen DT, Wynia MK, Moloney RM, **Alexander GC**. Physician knowledge of the FDA-approved indications of commonly prescribed drugs: results of a national survey. *Pharmacoepidemiology and Drug Safety*. 2009;18:1094-100. PMID: 19697444

59. Caskey R, Lindau ST, **Alexander GC**. Knowledge and early adoption of the HPV vaccine among adolescent girls and young women: results of a national survey. *Journal of Adolescent Health*. 2009;45:453-462. PMID: 19837351
- Editorial: Rodewald LE, Orenstein WA. Vaccinating adolescents – new evidence of challenges and opportunities. *Journal of Adolescent Health*. 2009;45:427-429. PMID: 19837347
60. Rathore SR, Ketcham J, **Alexander GC**, Epstein AJ. Influence of Patient Race on Physician Prescribing Decisions: A Randomized On-line Experiment. *Journal of General Internal Medicine*. 2009;11:1183-1191. PMCID: PMC2771231
61. Rabbani A, **Alexander GC**. Cost savings associated with filling a three month supply of prescription medicines. *Applied Economics and Health Policy*. 2009;7:255-264. PMID: 19905039
62. Torke AM, Siegler M, Abalos A, Moloney R, **Alexander GC**. Physicians' experience with surrogate decision making for hospitalized adults. *Journal of General Internal Medicine*. 2009;24:1023-1029. PMCID: PMC2726893
63. Rabbani A, **Alexander GC**. The impact of family structure on stimulant use among children with Attention Deficit Hyperactivity Disorder. *Health Services Research*. 2009;44:2060-2078. PMID: 19732168
64. **Alexander GC**, Humensky J, Guerrero C, Park H, Loewenstein G. Physician narcissism, ego threats, and confidence in the face of uncertainty. *Journal of Applied Social Psychology*. 2010;40:947-955.
65. Dorsey R, Rabbani A, Gallagher SA, Conti R, **Alexander GC**. The impact of black box warnings on the use of atypical antipsychotic medicines. *Archives of Internal Medicine*. 2010;170:96-103. PMID 20065205
- Editorial: Rochon PA, Anderson GM. Prescribing optimal drug therapy for older people: sending the right message. *Archives of Internal Medicine*. 2010;170:103-106. PMID: 20065206
66. Basu A, Yin W, **Alexander GC**. The impact of Medicare Part D on Medicare-Medicaid dual-eligible beneficiaries' prescription utilization and expenditures. *Health Services Research*. 2010;45:133-151. (National Bureau of Economic Research [NBER] Working Paper #W14413) PMID: 20002765
67. Cohen A, Rabbani A, Shah N, **Alexander GC**. Changes in glitazone use among office-based physicians in the United States, 2003-2009. *Diabetes care*. 2010;33:823-825. PMCID: PMC2845035
68. Torke AM, Moloney R, Siegler M, Abalos A, **Alexander GC**. Physicians' views on the importance of patient preferences in surrogate decision making. *Journal of the American Geriatrics Society*. 2010;58:533-538. PMID: 20158556
69. Tseng C, Brook RH, **Alexander GC**, Hixon A, Keeler E, Mangione CM, Chen R, Jackson E, Adams Dudley R. Physicians' use of health information technology and knowledge of formularies, prescription copayments, and retail drug prices. *American Journal of Managed Care*. 2010;16:e105-e110. PMID: 2037031
70. Lale A, Moloney RM, **Alexander GC**. Academic medical centers and underserved communities: modern complexities of an enduring relationship. *Journal of the National Medical Association*. 2010;102:605-613. PMID: 20690324

71. Saunders MR, Cagney KA, Ross LF, Alexander GC. Neighborhood Poverty, Racial Composition and Renal Transplant Waitlist. *American Journal of Transplantation*. 2010;10:1912-1917. PMID: 20659097
72. Qato DM, Lindau ST, Conti RM, Schumm P, **Alexander GC**. Racial and ethnic disparities in cardiovascular medication use among older adults in the United States. *Pharmacoepidemiology and Drug Safety*. 2010;19:834-842. PMID: 20681002
73. Shah ND, Montori VM, Krumholz HM, Tu K, **Alexander GC**, Jackevicius CA. Geographic Variation in the Response to FDA Boxed Warnings for Rosiglitazone. *N Engl J Med*. 2010;22:2081-2084. PMID: 21083379
74. **Alexander GC**, Gallagher SA, Mascola A, Moloney RM, Stafford RS. Increasing off-label use of antipsychotic medicines, 1995-2008. *Pharmacoepidemiology and Drug Safety*. 2011;20:177-84. PMCID: PMC3069498
75. **Alexander GC**, O'Connor AB, Stafford RS. Enhancing prescription drug innovation and adoption. *Annals of Internal Medicine*. 2011;154:833-837. PMID: 21690598
76. Liu FX, **Alexander GC**, Crawford SY, Pickard AS, Hedeker D, Walton SM. Impact of Medicare Part D on Emergency Department Use, Hospitalizations, and Preference-based Health Utility. *Health Services Research*. 2011;46:1104-1123. PMID: 21609328
77. Higashi AS, Zhu S, Stafford RS, **Alexander GC**. National trends in outpatient asthma treatment, 1997-2009. *Journal of General Internal Medicine*. 2011;26:1465-70. Epub 2011 Jul 16. PMID: 21769507
78. Redmann AJ, Brasel KJ, **Alexander GC**, Schwarze ML. Use of Advanced Directives for High Risk Operations: A National Survey of Surgeons. *Annals of Surgery*. 2012;255:418-423. PMID: 22167006
79. Qato DM, **Alexander GC**. Post-Marketing Drug Safety and the Food and Drug Administration's Risk Evaluation and Mitigation Strategies. *JAMA*. 2011;306:1595-1596.
80. Brush DR, Brown CE, **Alexander GC**. Critical care physicians' approaches to negotiating with surrogate decision makers: a qualitative study. *Critical Care Medicine*. 2012;40:1080-1087. PMID: 22080645

Editorial: Siegel MD, Perez MT. Within the black box: Exploring how intensivists resolve conflict at the end-of-life. *Critical Care Medicine*. 2012;40:1339-1340.
81. Pillarella J, Higashi A, **Alexander GC**, Conti R. Trends in the use of atypical antipsychotics for the treatment of bipolar disorder in the United States, 1998-2009. *Psychiatric services*. 2012;63:83-86.
82. Garfield CF, Dorsey ER, Zhu S, Huskamp HA, Conti R, Dusetzina SB, Higashi A, Perrin J, **Alexander GC**. U.S. Trends in the Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder, 2000-2010. *Academic Pediatrics*. 2012;12:110-116.
83. Ross JS, Jackevicius CA, Krumholz HM, Ridgeway JL, Montori VM, Alexander GC, Zerzan JT, Fan J, Shah ND. State Medicaid Programs Did Not Make Use Of Prior Authorization To Promote Safer Prescribing After Rosiglitazone Warning. *Health Affairs*. 2012;31:188-98.

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- Editorial: Dal Pan GJ. Communicating the risks of medicines: time to move forward. *Medical Care*. 2012;50:463-465.
85. Pham-Kanter G, **Alexander GC**, Nair K. Effect of financial disclosure laws on physician prescribing. *Archives of Internal Medicine*. 2012;172:819-821.
86. Paczynski RP, **Alexander GC**, Chinchilli VM, Kruszewski SP. Quality of evidence in drug compendia supporting off-label use of typical and atypical antipsychotic medications. *International Journal of Risk and Safety in Medicine*. 2012;24:137-146.
87. Kirley K, Qato DM, Kornfield R, Stafford RS, **Alexander GC**. National trends in oral anticoagulant use in the United States, 2007-2011. *Circulation: Cardiovascular Outcomes and Quality*. 2012;5:615-621.
88. **Alexander GC**, Lambert BL. Is Treatment Heterogeneity an Achilles' Heel for Comparative Effectiveness Research? *Pharmacotherapy*. 2012;32:583-585.
89. Brush DR, Rasinski KA, Hall JB, **Alexander GC**. Recommendations to limit life support: A national survey of critical care physicians. *American Journal of Respiratory and Critical Care Medicine*. 2012;186:633-639.
- Editorial: Hillman KM. Limitations at the End of Life. *American Journal of Respiratory and Critical Care Medicine*. 2012;186:581-582.
90. Schwarze ML, Redmann AJ, **Alexander GC**, Brasel KJ. Surgeons expect patients to buy-in to postoperative life support preoperatively: Results of a national survey. *Critical Care Medicine*. 2012;41:1-8.
- Editorial: Buchman TG. Informal Contracts, Shared Decision Making, and the Covenant of Care. 2012;41:326-327.
91. **Alexander GC**, Kruszewski SP, Webster DW. Rethinking Opioid Prescribing to Protect Patient Safety and Public Health. *JAMA*. 2012;308:1865-1866.
92. Schwarze ML, Redmann AJ, Brasel KJ, **Alexander GC**. The role of surgeon error in withdrawal of postoperative life support. *Annals of Surgery*. 2012;256:10-15.
93. Dusetzina SB, Busch AB, Conti RM, Donohue JM, **Alexander GC**, Huskamp HA. Changes in Antipsychotic Use among Patients with Severe Mental Illness after an FDA Advisory. *Pharmacoepidemiology and Drug Safety*. 2012;21:1251-1260.
94. Graziul C, Gibbons R, **Alexander GC**. Association between the commercial characteristics of psychotropic drugs and the probability of their off-label use. *Medical Care*. 2012;50:940-947.
95. deSouza JA, Polite B, Perkins M, Meropol NJ, Ratain MJ, Newcomer LN, **Alexander GC**. Unsupported off-label chemotherapy in metastatic colon cancer. *BMC Health Services Research*. 2012;12:481.

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97. Tan J, **Alexander GC**, Segal J. Academic Centers Play A Vital Role in the Study of Drug Safety and Effectiveness. Clinical Therapeutics. 2013;35:380-384.
98. Kornfield R, Donohue J, Berndt ER, **Alexander GC**. Promotion of Prescription Drugs to Consumers and Providers, 2001-2010. PLOS One. 2013;8:1-7.
99. Olson TJP, Brasel KJ, Redmann AJ, **Alexander GC**, Schwarze ML. Surgeon-Reported Conflict With Intensivists About Postoperative Goals of Care. JAMA Surgery. 2013;148:29-35.
100. Dusetzina SB, Cook BL, Busch AB, **Alexander GC**, Huskamp HA. Racial-Ethnic Differences in Incident Olanzapine Use After an FDA Advisory for Patients With Schizophrenia. Psychiatric Services. 2013;64:83-87.
101. Kornfield R, Watson S, Higashi AS, Conti RM, Dusetzina SB, Garfield CF, Dorsey ER, Huskamp HA, **Alexander GC**. Impact of FDA Advisories on Pharmacologic Treatment of ADHD, 2004-2008. Psychiatric Services. 2013;64:339-46.
102. Dusetzina SB, **Alexander GC**, Freedman RA, Huskamp HA, Keating NL. Trends in co-prescribing of antidepressants and tamoxifen among women with breast cancer, 2004-2010. Breast Cancer Research and Treatment. 2013;137:285-296.
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104. Fain K, Daubresse M, **Alexander GC**. The Food and Drug Administration Amendments Act (FDAAA) and Postmarketing Commitments. JAMA. 2013;310:202-204.
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318. Ardeshirrouhanifard S, An H, Goyal RK, Raji M, Segal J, **Alexander GC**, Mehta HB. Use of Oral Anticoagulants Among Individuals with Cancer and Atrial Fibrillation in the United States, 2009-2016. Under development.
319. Andersen KM, An H, Bates B, Joseph C, et al. Use of Chronic Immunosuppressive Medicines and COVID-19 Outcomes: A Retrospective Cohort Study Using the National Covid Cohort Collaborative (N3C). Under development.

Articles and Editorials not peer reviewed (names of trainees are underlined)

1. **Alexander GC**. "On Remaining Human." *Becoming Doctors*. Student Doctors Press, La Grange Park, IL: pp 226-228, 1995 (essay).
2. **Alexander GC**, Weiss A, George S. "Virtual Medical School." *The New Physician*. Oct 1996: 16-17 (manuscript).
3. **Alexander GC**. Course Guide – Caring for Patients Near the End-of-Life. Case Western Reserve University - School of Medicine, 1997;1-88 (curriculum).

4. **Alexander GC**, Weiss A. Providing laptops to promote computer use: lessons learned. *Academic Medicine*. 1998;73:224-225 (letter to editor).
5. **Alexander GC**. Patient care and student education. *Virtual Mentor: Ethics Journal of the American Medical Association*. Available at: <http://www.ama-assn.org/ama/pub/category/7678.html> Accessed April 26, 2002 (invited commentary).
6. **Alexander GC**, Kwiatkowski C. Diagnosing and managing adverse drug events in hospitalized patients. *Topics in Drug Therapy* (University of Chicago). 2003;45:1-8. (manuscript)
7. **Alexander GC**, Casalino LP, Metlzer DO. Factors in studying patient-physician communication. *JAMA*. 2003;290:2544. (letter)
8. **Alexander GC**. Prescriptions of sleep. *Canadian Family Physician*. 2004;50:543-545. (essay)
9. **Alexander GC**. Unnecessary tests and ethics of quality of care. *Virtual Mentor: Ethics Journal of the American Medical Association*. Available at: <http://www.ama-assn.org/ama/pub/category/12470.html> Accessed June 2, 2004. (invited commentary)
10. Sayla M, **Alexander GC**. An annotated bibliography exploring prescription cost-sharing. Prepared for the national meeting of the Society of General Internal Medicine. June, 2005. (annotated bibliography)
11. **Alexander GC**. Issue brief: Many physicians engaged in addressing health disparities. Developed on behalf of the Commission to End Health Disparities, April 2005. (issue brief)
12. **Alexander GC**. Geographic barriers and access to care. *Virtual Mentor: Ethics Journal of the American Medical Association*. 2005;7. Available at: <http://www.ama-assn.org/ama/pub/category/15218.html> Accessed July 5, 2005. (invited commentary).
13. **Alexander GC**. A crash course? What happens when a patient's medical and economic best interests collide? *Virtual Mentor: Ethics Journal of the American Medical Association*. 2006;8:147-149. (invited commentary)
14. Smith PJ, **Alexander GC**, Siegler M. Should editorials in peer-reviewed journals be signed? *Chest*. 2006;129:1395-1396. (Invited editorial)
15. **Alexander GC**, Lantos JD. Bioterrorism, public service, and the duty to treat. *Cambridge Quarterly*. 2006;15:422-423. (Invited commentary)
16. Torke AM, **Alexander GC**. Can healers have private lives? *Virtual Mentor: Ethics Journal of the American Medical Association*. 2006;8:441-448. Available at: <http://www.ama-assn.org/ama/pub/category/16375.html> Accessed July 26, 2006. (Invited commentary)
17. **Alexander GC**, Lantos J. The nuances of self-disclosure. Response to: "Physician self-disclosure in primary care visits: enough about you, what about me?" *Arch Intern Med*. 2008;168:242-244. (Letter to editor)
18. Torke A, **Alexander GC**, Lantos J, Siegler M. Response to letter regarding "The doctor-surrogate relationship." *Archives of Internal Medicine*. 2008;168:241-242. (Letter to editor)

19. **Alexander GC**. Dilemmas for a reason. *Journal of Clinical Ethics*. 2008;19:70-71. (Invited commentary)
20. Lale A, **Alexander GC**. The Urban Health Initiative: a story of one academic medical center and the underserved. *SGIM Forum*. December 2008. (Invited editorial)
21. Torke AM, **Alexander GC**, Lantos J. Substituted judgment. *Journal of General Internal Medicine*. 2009;24:146. (Letter to editor, reply).
22. Saunders M, **Alexander GC**. Turning and churning: loss of health insurance among adults in Medicaid. *Journal of General Internal Medicine*. 2009;24:133-4. (Invited editorial)
23. Walton SM, Schumock GT, Lee KV, **Alexander GC**, Meltzer D, Stafford RS. Importance of distinguishing supported and unsupported off-label use. *Archives of Internal Medicine*. 2010;170:657-658. (Letter to editor, reply)
24. Qato DM, **Alexander GC**. Response to: Hartung DM, Evans D, Haxby DG, Kraemer DF, Andeen G, Fagnan LJ. Effect of Drug Sample Removal on Prescribing in a Family Practice Clinic *Ann Fam Med* 2010 8:402-409. (Letter to editor, reply)
25. **Alexander GC**. Clinical prescribing (and off-label use) in a second-best world. *Medical care*. 2010;48:285-287. (Invited editorial)
26. Health IQ:2011. The Frontiers of Healthcare Advancement. IMS Institute for Healthcare Informatics. Diffusion of Innovation: Patterns and Effects. (Invited Chapter).
27. **Alexander GC**. Researcher's Corner: Talk Early and Often. *SGIM Forum*. 2011;34:5.
28. Dusetzina S, **Alexander GC**. Drug vs. Class-Specific Black Box Warnings: Does One Bad Drug Spoil the Bunch? *Journal of General Internal Medicine*. 2011;26:570-572. (Invited editorial)
29. **Alexander GC**. Seeding trials and the subordination of science. *Arch Intern Med*. 2011;171:1107-1108. (Invited editorial)
30. deSouza JA, **Alexander GC**. Unsupported off-label use of cancer therapies: new challenges in the era of biopharmaceuticals. *Expert Review of Pharmacoeconomics & Outcomes Research*. 2011;11:495-498. (Invited editorial)
31. Qato DM, **Alexander GC**. Just Because It's Low Cost Doesn't Mean It's Accessible. *Journal of General Internal Medicine*. 2012;27:1233-1234. (Invited editorial)
32. Tan J, **Alexander GC**, Segal JB. Academic Centers Play a Vital Role in the Study of Drug Safety and Effectiveness. *Clin Ther*. 2013;35:380-384. (Invited editorial)
33. **Alexander GC**. Curious Conundrums of Off-label Prescribing. *PM&R*. 2013;5:882-889. (Invited editorial)
34. Fain K, **Alexander GC**. Are FDA Prescription Drug Safety Plans Working: A Case Study of Isotretinoin. *Pharmacoepidemiology and Drug Safety*. Pending publication. (Invited editorial)

35. Fain K, **Alexander GC**. Are FDA Prescription Drug Safety Plans Working: A Case Study of Isotretinoin. *Pharmacoepidemiology and Drug Safety*. 2014;23:440-441. (Invited response to letter to the editor).
36. Fain K, **Alexander GC**. Drug Postmarketing Studies--Reply. *JAMA*. 2013;310:2459-2460. (Invited response to letter to the editor)
37. **Alexander GC**. Capsule Commentary on Faerber and Kreling, "Content Analysis of False and Misleading Claims in Television Advertising for Prescription and Nonprescription Drugs". *Journal of General Internal Medicine*. 2014;29:180. (Invited commentary)
38. Fain K, **Alexander GC**. Mind the Gap: Understanding the Effects of Pharmaceutical Direct-to-Consumer Advertising. *Medical Care*. 2014;52:291-293. (Invited editorial)
39. Hwang CS, **Alexander GC**. Commentary on "Tamblyn R, Egualé T, Huang A, Winslade N, Doran P. The incidence and determinants of primary nonadherence with prescribed medication in primary care: a cohort study. *Ann Intern Med*. 2014;160:441-50." Failure to Fill a First Prescription of a New Medication is Common in Primary Care Settings. *BMJ Evidence Based Medicine*. 2014;19:196. (Invited commentary)
40. Fain K, **Alexander GC**. Disposing of Medicines Safely. *American Journal of Public Health*. 2014;104:e2-3. (Letter to the editor)
41. Daubresse M, Fain K, **Alexander GC**. The Conversation. Upscheduling Hydrocodone. Pending publication. (Invited commentary)
42. Riggs KR, **Alexander GC**. Cost Containment and Patient Well-Being. *Journal of General Internal Medicine*. 2015;30:701-702. (Invited editorial)
43. **Alexander GC**, Keyes E. The Best Medicine: A Good Relationship With Your Doc. *The Baltimore Sun*. May 7, 2015. (Op-Ed)
44. Lyapustina T, **Alexander GC**. The Prescription Opioid Epidemic: A Problem of Our Own Making. *The Pharmaceutical Journal*, 13 June 2015, Vol 294, No 7866, online | DOI: 10.1211/PJ.2015.20068579 (Invited editorial)
45. Iyer G, **Alexander GC**. Cardiovascular Outcomes Associated with Clarithromycin. *BMJ*. 2016;352:i23 (Invited editorial)
46. Dy S, Wegener S, **Alexander GC**, Suarez-Cuervo C, Bass E. Comparative Effectiveness of Alternative Strategies for Decreasing Initiation of Opioids for Managing Chronic Pain. *PCORI Topic Brief*. The Johns Hopkins Evidence Based Practice Center. February 2016.
47. Qato DM, **Alexander GC**. Fish Oils and Bleeding: Where Is the Evidence? – In Reply. *JAMA Internal Medicine*. 2016;176(9):1406-1407.
48. Barrett K, Lucas E, **Alexander GC**. How Polypharmacy Has Become a Medical Burden Worldwide. *The Pharmaceutical Journal*. June 9, 2016. Available at: <http://www.pharmaceutical-journal.com>

49. Murimi IB, **Alexander GC**. Opiate overdose as a patient safety problem [Perspective]. AHRQ PSNet [serial online]. May 2017. Available at: <https://psnet.ahrq.gov/perspectives/perspective/225>.
50. **Alexander GC**. In Ali AK, Hartzema AG (eds). Post-Authorization Safety Studies of Medicinal Products: The PASS Book. In press. (Forward)
51. Qato DM, **Alexander GC**, Lindau ST. AAP's Section on Integrative Medicine Suggests a More Balanced Approach to Dietary Supplement Data – In Reply. Pediatrics. In press.
52. Herder MR, Doshi P, Wallach JD, et al. FDA to Begin Releasing Clinical Study Reports in Pilot Programme. BMJ. 2018;360:k294. (Letter to the editor)
53. Mudumbai S, Stafford RS, **Alexander GC**. Having Surgery? Beware of Risk from Post-Op Opioids. USA Today. February 12, 2019. (Op-Ed)
54. **Alexander GC**, Sharfstein J. Opioid epidemic: Fighting addiction and chronic pain together to save lives. USA Today. April 25, 2019. (Op-Ed)
55. **Alexander GC**, Kolodny A. In Reply: Initial Opioid Prescriptions Among U.S. Commercially Insured Patients, 2012-2017. New England Journal of Medicine. May 2019. (Letter to editor)
56. Heyward J, Sharfstein S, **Alexander GC**. Assessing the Opioid Analgesic Risk Evaluation and Mitigation Strategy Program—Reply. JAMA Internal Medicine, 2020. (Invited response to letter to the editor)
57. **Alexander GC**, Kesselheim AS, Moore TJ. Searching for an Effective Covid-19 Treatment: Promise and Peril. STAT. April 10, 2020. (Op-Ed)
58. Rashidi E, Andersen KM, Akenroye A, Xu Y, **Alexander GC**, Mehta H. In Reply: In-Hospital Use of Statins Is Associated with a Reduced Risk of Mortality among Individuals with COVID-19 – Reply. Cell Metabolism. September 2020. (Comment to Editorial Board)
59. Qato DM, Alexander GC, Lindau ST. Access to Pharmacist-Prescribed and Emergency Contraception in Los Angeles County, 2017—Reply. Health Affairs, 2020. (Invited response to letter to the editor)
60. Wang L, Paller CJ, Hong H, De Felice A, Alexander GC, Brawley O. Comparison of Systemic Treatments for Metastatic Castration-Sensitive Prostate Cancer: A Systematic Review and Network Meta-analysis. – In Reply.

Monographs, book chapters and other scientific reports

1. **Alexander GC**, Wynia MK. Survey research in bioethics. In “Empiric Methods for Bioethics: A Primer.” Eds: Jacoby L, Siminoff LA. Elsevier Press, New York, New York, 2007”.
2. Quinn MT, Gnepp J, **Alexander GC**, Hollingsworth D, O’Connor KG, Lang W, Klayman J, Meltzer DO. Design and Evaluation of Worksite Promotions of Organ Donation: Real-world Challenges and Practical Solutions. In “Understanding organ donation: applied behavioral science perspectives.” Eds: Siegel JT, Alvaro EM. Blackwell/Claremont Applied Social Psychology Series. Wiley-Blackwell, Chichester, West Sussex, United Kingdom, 2010.
3. Saunders M, **Alexander GC**, Siegler M. Clinical ethics and the practice of hospital medicine. In “Principles and Practice of Hospital Medicine.” Eds: McKean, Ross, Dressler, Brotman, Ginsberg. McGraw-Hill Companies, 2012 (2nd Edition printed 2016).
4. **Alexander GC**, Frattaroli S, Gielen AC, eds. The Prescription Opioid Epidemic: An Evidence-Based Approach. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015
5. Citizen Petition to the Food and Drug Administration (Signatory). Requesting that the Commission to the FDA place a black box warning on pharmaceuticals in the opioid and benzodiazepine classes warning patients of the potential serious risks with concomitant use of both classes of medications. Submitted February 22, 2016. Petition granted August 31, 2016. Petition available at: [http://health.baltimorecity.gov/sites/default/files/Final%20Draft%20FDA%20petition-Full%20Co-Signers-2.19.16%20\(2\)%20\(1\).pdf](http://health.baltimorecity.gov/sites/default/files/Final%20Draft%20FDA%20petition-Full%20Co-Signers-2.19.16%20(2)%20(1).pdf) (Accessed September 1, 2016).
6. Working Group Member. Transparency at the U.S. Food and Drug Administration: Recommendations to Support the Development of Safe and Effective Medical Products. October 2016.
7. Working Group Member. Partnership Forum: Navigating Innovations in Diabetes Care. Journal of Managed Care and Specialty Pharmacy. December 2016.
8. Sharfstein JM, Miller JD, Davis AL, Ross JS, McCarthy ME, Smith B, Chaudhry A, Alexander GC, Kesselheim AS. Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products. January 22, 2017.
9. **Alexander GC**, Frattaroli S, Gielen AC, eds. The Opioid Epidemic: From Evidence to Impact. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2017.
10. Bicket MC, **Alexander GC**. Prescribing Guidelines and Opioid Stewardship. In “The Public Health Guide to Ending the Opioid Epidemic.” Prescribing Guidelines and Opioid Stewardship. In: A Public Health Guide to Ending the Opioid Epidemic. Edited by Michael R. Fraser PhD MS, Jay C. Butler MD and Philicia Tucker MPH, Oxford University Press (2019). DOI: 10.1093/oso/9780190056810.003.0023

Other

Designed and hosted a web site devoted to patient education and empowerment regarding prescription costs and polypharmacy. Previously available (2005-2012) at: <http://prescriptions.bsd.uchicago.edu/>

CURRICULUM VITAE
G. Caleb Alexander, MD, MS

PART II

TEACHING (Johns Hopkins University, 2012-present)

Undergraduate students

- Ian Day; Academic Advisor for Special Public Health Honors Thesis, 2020-2021

Graduate students (iMPH or MPH Advisor)

- Vibhuti Arya, PharmD; Academic Advisor for Part-time iMPH Program, 2012-2016
- Haley Gibbs, PharmD; Academic Advisor for Part-time iMPH Program, 2012-2015
- Ayu Katada; Academic Advisor for MPH Program (MPA/MBA Dual Degree), 2012-2014
- Etka Argawal; Academic Advisor for MPH Program in Epidemiologic and Biostatistical Methods for Public Health and Clinical Research, 2013-2014
- Lee Meller, MD; Academic Advisor for Part-time iMPH Program, 2013-2014
- Sharonjit Sagoo, PharmD; Academic Advisor for Part-time iMPH Program, 2015-
- Carolyn Tieu, PharmD, Academic Advisor for MPH Program, 2016-2017
- Ken Ogasawara, PhD, Academic Advisor for MPH Program, 2016-2017
- Denise Lepley, Academic Advisor for Part-time iMPH Program, 2017-2018
- Juan Franco, MD, Academic Advisor for Part-time iMPH Program, 2018-2020
- Varsha Lalchandani, Academic Advisor for Part-time iMPH Program, 2018-
- Rachel McFadden, Academic Advisor, Bloomberg American Health Fellow, 2019-
- Michael Kennedy, Academic Advisor, Bloomberg American Health Fellow, 2020-
- Sindhura Karlapudi, MBBS, Academic Advisor for MPH Program, 2020-2021

Graduate students (MHS Advisor)

- Francine Chingcuanco; Academic Advisor for MHS Program in Cardiovascular Epidemiology, 2014-2016
- Geetha Ayer; Academic Advisor for ScD Program in Cardiovascular Epidemiology, 2014-2016
- Meijia Zhou; Academic Advisor for MHS Program in General Epidemiology and Methodology, 2012-2014
- Jeffrey Yu; Academic Advisor for MHS Program in Health Economics, 2017-2018
- Hanzhe Zhang; Academic Advisor for MHS Program in General Epidemiology and Methodology, 2017-2020

Graduate students (Capstone or Thesis Advisor)

- Ayu Katada; Academic Advisor for MPH Program (MPA/MBA Dual Degree), 2012-2014
- Jinhee Moon, MHS; Capstone Advisor for MPH Program, 2012-2013 (Outstanding Achievement Award)
- Steven Jones; Capstone Advisor for MPH Program, 2012-2013
- David Nartey; Capstone Advisor for MPH Program, 2012-2013
- Tatyana Lyapustina; Capstone Advisor for MPH Program (MD/MPH Dual Degree), 2014-2015
- James Goldberg; Capstone Advisor for iMPH Program, 2015-2016
- Zoya Fansler; Capstone Advisor for Part-time iMPH Program, 2015-2016
- Jeong Ah Cho; Capstone Advisor for MPH Program (MPH/MBA Dual Degree), 2016-2018

- Shengyuan (David) Luo; Thesis Co-Advisor for MHS Program, 2016-2018
- Yunwen Xu; Thesis Advisor for MHS Program, 2016-2018
- Omar Mansour; Thesis Advisor for MHS Program, 2016-2018
- Jeffrey Rollman; Capstone Advisor for MPH Program, 2017-2018
- Nune Makarova; Capstone Advisor for MPH Program, 2017-2018
- Nisha Parikh; Capstone Advisor for MPH Program, 2018-2019
- Xintong Li; Thesis Advisor for MHS Program, 2017-2019
- Juan Franco, MD, Capstone Advisor for Part-time iMPH Program, 2018-2019
- Paul O'Malley, Capstone Advisor for Part-time iMPH Program, 2019
- Stephen Sander, Capstone Advisor for Part-time iMPH Program, 2020
- Margarita Sotelo, Capstone Advisor for Part-time iMPH Program, 2021

Graduate Students (Doctoral Advisor or Dissertation Committee Member)

- Kevin Fain, Dissertation Committee Member (DrPH/Epidemiology), 2012-2015
- Jingwen Tan, Dissertation Committee Member (PhD/Clinical Epidemiology), 2012-2016
- Shilpa Viswanathan, Dissertation Committee Member (PhD/Clinical Epidemiology), 2012-2015
- Richard Scott Swain, Dissertation Committee Member (PhD/Clinical Epidemiology), 2013-2015
- Christopher Kaufman, Dissertation Committee Member (PhD/Mental Health), 2013-2015
- Christine Buttorff, Dissertation Committee Member (PhD/Health Policy and Management), 2012-2014
- Remington Nevin, Dissertation Committee Member (PhD/Mental Health), 2014-2017
- Mariana Socal, Dissertation Committee Member (PhD/Mental Health), 2014-2017
- Lisa Selker, Dissertation Committee Member (PhD/University of North Carolina Rollings School of Public Health), 2015-2020
- Sheriza Bakst, Doctoral Advisor (PhD/Epidemiology), 2015-2018
- Alex Secora, Doctoral Advisor (PhD/Epidemiology), 2016-2019
- Lucy Qiao, Doctoral Co-Advisor (PhD/Epidemiology), 2017-2021
- Kathleen Anderson, Doctoral Co-Advisor (PhD/Epidemiology), 2018-
- Jiajun Wen, Dissertation Committee Member (PhD/Epidemiology), 2018-
- Thomas Metkus, Dissertation Committee Member (PhD/Graduate Training Program in Clinical Investigation [GTPCI]), 2019-
- Lin Wang, Doctoral Co-Advisor (PhD/Epidemiology), 2019-2021
- Katherine Ozenberger, Dissertation Committee Member (PhD/University of Illinois School of Pharmacy), 2019-
- Bingkai Wang, Dissertation Committee Member (PhD/Biostatistics), 2020-2021
- Lisa Dwyer, Part-time/online DrPH Program, Academic Advisor, 2020-
- Jennifer Black, Part-time/online DrPH Program, Academic Advisor, 2020-
- Brendan Rabideau, Dissertation Committee Member (PhD/Health Policy & Management), 2019-
- Ahizechukwu C Eke, Dissertation Committee Member (PhD/GTPCI), 2019-2021

Other Trainees (Post-doctoral or beyond)

- Kevin Riggs, MD; Mentor for research program examining generic utilization and effect of drug coupons on drug utilization and expenditures, 2013-2016
- Mark Bicket, MD; Mentor of career development award activities focused on utilization, safety and effectiveness of prescription opioids in peri-operative setting, 2016-2018

Classroom Instruction

- Designer and Instructor, Pharmacoepidemiology: Drug Utilization, 2014-present (340.684.01)

- Co-Instructor, Design of Epidemiologic Studies: Proposal Development & Critique, 2015-present (340.715.01)
- Lecturer, Epidemiology of Aging (340.616.01)
- Lecturer, Pharmacoepidemiology Methods (340.682.01)
- Small Group Facilitator: Clinical Epidemiology, Johns Hopkins School of Medicine, 2014-2016
- Graduate Summer Institute of Epidemiology and Biostatistics: Pharmacoepidemiology (340.617.11)
 - Lecturer, 2012-2016
 - Designer and Co-Instructor, 2017-present
 - Excellence in Teaching Distinction for Course
- Lecturer, Graduate Training Program in Clinical Investigation, Principles of Drug Development, 2017-present

Other significant teaching

- Participate in informal mentoring with dozens of students through works in progress, journal clubs and seminar series within the Departments of Epidemiology (School of Public Health) and the Division of General Internal Medicine (Johns Hopkins Medicine)
- Co-lead Special Seminar Series “Pharmaceutical Safety, Value and Innovation” sponsored by Center for Drug Safety and Effectiveness

TEACHING (University of Chicago, 2001-2012)

Undergraduate students

Mounica Yanamandala, University of Chicago, Primary mentor (2009-2011)
Regina Depietro, University of Chicago, Primary mentor (2009-2011)
Mateusz Ciejska, University of Chicago, Primary mentor (2009-2010)
Sarah Gallagher, University of Chicago, Primary mentor (2008-2009)
Maliha Darugar, University of Chicago, Primary mentor (2003-2006)
Nadiah Mohajir, Harris School for Public Policy, Honors thesis advisor (2002-2003)
Diane McFadden, University of Chicago, Primary mentor (2002-2003)

Graduate students

Frank Liu, Department of Pharmacy Administration, College of Pharmacy, University of Illinois at Chicago, Thesis committee (2008-2010)
Teri Arthur, PhD, MSW, Social Services Administration, Dissertation Committee (2004-2008)
Carolanne Dai, PhD, Harris School of Public Policy, Dissertation Committee (2002-2007)
Sachiko Kuwabara, BA, Masters of Arts, University of Chicago (2004-2006)
Melissa Brown, BA, Masters of Arts, University of Chicago (2005-2006)

Medical students

Erica MacKenzie, BA, Research Mentor (2011)
Daniel Kozman, BA, Research Mentor (2010)
Jessica Pirella, BA, Research Mentor (2010)
Andrew Cohen, BA, Research Mentor (2009)
Michelle Stacey, BA, Research Mentor (2009)
Karen Draper, BA, Research Mentor (2008)
Allison Lale, BA, Research Mentor (2008)
Rob Guzy, MD, PhD, Residency Advisor (2007)
Susanne Phongsak, BA, Research Mentor (2006)

Cesar Guerrero, BA, Research Mentor (2006)
Patrick Lang, BA, Research Mentor (2004)
Charles Kaufmann, MD, PhD, Residency Advisor (2004-2005)
Stephanie Takahashi, MD, Residency Advisor (2005-2006)

Residents

Victoria Wong, MD, Editorial fellow, Journal of General Internal Medicine (2009-)
Femi Aboyeji, MD, Research elective mentor (2007)

Fellows

Jonas DeSouza, MD (2010-2012)
David Brush, MD (2009-2012)
Milda Saunders, MD, MPH (2008-2012)
Health services research fellows. University of Chicago (2004-2012)
MacLean Center for Clinical Medical Ethics, Lecturer (2003-2012)
Rachel Caskey, MD, Primary mentor (2006-2008)
Alexia Torke, MD, HRSA Fellow, Primary mentor (2005-2007)
Tumaini Colker, MD, MBA, Robert Wood Johnson Clinical Scholar (2005-2006)
Gretchen Schwarze, MD, MPH, Vascular Surgery (2003-2006)

Post-doctoral fellows

Dima Qato, PharmD, MPH, PhD (2011)
Atonu Rabbani, PhD (2007-2009)

Classroom Instruction

Lecturer, The doctor-patient relationship in clinical practice (2002-2011)
Lecturer, MacLean Center for Clinical Ethics Summer Intensive (2003-2011)
Designer and lecturer, Research Design Course for RWJF Clinical Scholars (2004-2006)
Designer and lecturer, Research Design Course for Fellow Summer Intensive (2004-2006)
Lecturer, Introductory Course on the fundamentals of health services research

Other significant teaching

Group leader for medical student summer research program (2004-2011)
National Youth and Leadership Forum, Faculty participant (2005-2010)
Participant in 1:1 Mentoring Program, Society of General Internal Medicine, 2007

RESEARCH GRANT AND CONTRACT PARTICIPATION

Current support

Grant: 5 R21AG058132-02; 9/15/18 – 8/31/20; National Institute on Aging (Andersen)
Purpose: To quantify the effect of drug utilization management in the Medicare Part D program

Grant: 3/1/2019 – 2/29/2020; Cardinal Health (Qato)
Purpose: To conduct a pilot study exploring the potential role of telepharmacy in improving medication adherence in urban areas

Grant: 1 T32 HL139426-01; 12/27/2017 – 12/26/2022; National Heart, Lung and Blood Institute (Alexander/Segal)
Purpose: To optimize the safe and effective use of medicines to treat heart, lung and blood diseases

Grant: R01DK115534-01A1; 8/01/18 07/31/22; National Institutes of Diabetes and Digestive and Kidney Diseases (Grams/Inker)

Purpose: To investigate the risk and benefits of specific medications across the range of kidney function within 5 large, global electronic health records

Grant: 1R01DA044987-01; 9/30/2017 – 7/31/2021; National Institutes of Drug Abuse (McGinty/Rutkow)

Purpose: To quantify the effect of state laws intended to curb high-risk opioid prescribing

Grant: 1R01DA042738-01; 02/01/17–11/30/20; National Institutes of Drug Abuse (Rutkow)

Purpose: To assess the association between clean indoor air laws, cigarette taxes, and use of smoking cessation treatments

Grant: 1 U01 FD005942-01; 9/1/2018-8/31/2022; Food and Drug Administration (Alexander)

Purpose: To enhance regulatory science through a unique FDA-academic partnership (CERSI)

Grant: 05/01/2019 – 04/30/2020; The Arnold Foundation (Andersen)

Purpose: To evaluate and advance policy recommendations to achieve a “fair price” of high cost prescription drugs

Past support (selected list)

Grant: 3R01DA044987-03S1; 8/1/2019 – 10/31/2019; National Institutes of Drug Abuse (McGinty/Rutkow)

Purpose: Landscape Review of U.S. Health Professional Pain Management Curricula

Grant: 8/1/17-4/30/19; The Arnold Foundation (Andersen)

Purpose: To evaluate and advance policies to achieve a “fair price” of high cost prescription drugs

Grant: 5/5/2017- 1/30/2018; Department of Health and Human Services/ASPE (Alexander)

Purpose: To describe the breadth and depth of coverage policies for acute and chronic back pain among a nationally representative selection of Medicaid, Medicare Advantage and commercial health plans

Grant: 7/1/2016-4/4/2017; AstraZeneca (Alexander)

Purpose: To quantify the disease burden and resource utilization associated with Systemic Lupus Erythematosus (SLE)

Grant: 12/2/2016-6/30/2017; AstraZeneca (Alexander)

Purpose: To characterize the association between organ damage, quality of life, and mortality among patients with Systemic Lupus Erythematosus (SLE)

Grant: ID# 72452; 2/15/2015-1/31/2017; Robert Wood Johnson Foundation (Rutkow)

Purpose: To understand role of interorganizational relationships, information sharing and legally established infrastructure on prescription drug monitoring programs’ function and impact within the public health system

Grant # U01FD005556: 09/15/15-08/31/16; Food and Drug Administration (Varadhan)

Purpose: To develop structural nested models to assess safety and effectiveness of generic drugs

Grant: 1 R01 HL 107345-01; 4/1/11-3/31/15; NHLBI (Alexander, Co-PI)

Purpose: To examine the effect of DTCA on prescription and non-prescription health care utilization

Grant: 1 R01 AG034187-01; 7/1/2012-6/30/2015; National Institutes on Aging (Kaestner)

Purpose: To determine if Part D Prescription Coverage Improves Health and Reduces Inpatient Use

Grant: 1 UO1 CE002499-01; 9/1/2014-9/1/2016; Center for Disease Control and Prevention (Alexander)

Purpose: To evaluate the effect of Florida's Pill-Mill Law on opioid prescribing, utilization and dispensing

Grant: ID# 24741; 7/1/2014-1/1/2016; Robert Wood Johnson Foundation (Alexander)

Purpose: To evaluate the effect of Prescription Drug Monitoring Programs on opioid prescribing, utilization and dispensing

Grant: 1 R01 HS 018960-01; 8/1/10-7/31/14; Agency for Health Care Quality and Research (Alexander)

Purpose: To assess the effect of FDA advisories on provider, patient, and firm behavior

Grant: 1 K08 HS15699-01A1; 2/01/06-2/01/11; Agency for Health Care Quality and Research (Alexander)

Purpose: To conduct a randomized trial to reduce patient's out-of-pocket prescription costs

Grant: Robert Wood Johnson Physician Faculty Scholars Award; 7/1/06-6/30/09; RWJ Foundation (Alexander)

Title: Development and evaluation of interventions to reduce patients' prescription costs

Contract: IMS Health Services Research Network; 10/1/10-12/31/11; IMS Health (Alexander)

Purpose: To develop and promote academic research network using IMS Health's data assets to address questions relevant to health care reform

Grant: UL1RR024999; 12/1/09-11/30/10; CTSA Institutional Pilot (Alexander)

Purpose: To quantify the impact of FDA advisories on psychotropic medication use among children

Grant: The University of Chicago Program for Pharmaceutical Policy; 2/01/05-6/1/09; The Merck Foundation (Meltzer)

Purpose: To foster innovative research at the University of Chicago in pharmaceutical policy with a focus on regulation, innovation, and technology assessment

Contract: HHSA 290 200 500 381; 9/16/05-9/15/10; Agency for Health Care Quality and Research (Schumock)

Title: Chicago Area Pharmaceutical Outcomes Research Consortium. Developing Evidence to Inform Decisions about Effectiveness: The DECIDE Network

Grant: The Greenwall Foundation; 7/1/10-6/30/11 (Alexander)

Purpose: To conduct a mixed-methods study to examine management of conflict between physicians and surrogates of critically ill adults

Grant: Center for Education and Research on Therapeutics (CERT); 09/01/07 – 3/31/11; Agency for Health Care Quality and Research (Meltzer)

Purpose: To create an education and research infrastructure that produces and disseminates knowledge to improve the effectiveness and cost-effectiveness of the use of therapeutics

Grant: Mixed-methods exploration of the adoption of the HPV Vaccine; 10/1/07-9/30/08; University of Chicago Program for Pharmaceutical Policy Pilot Grant (Alexander)

Purpose: To establish prevalence and determinants of HPV vaccine uptake

Contract: HHSA29020050038I; 9/15/06-1/29/07; AHRQ (Walton)

Purpose: To develop a method of prioritization of research efforts on off-label drug use

Grant: R39OT03411-01-00; 10/01/04-09/30/07; Health Resources and Services Administration Division of Transplantation (Lang)

Purpose: To develop, implement, and assess workplace intervention to increase organ donor intention

Grant: The Medicaid Pharmacy Cost Containment and Patient Outcomes; 7/1/06-6/30/07; Center for Health and the Social Sciences - University of Chicago Pilot Grant (Alexander)

Purpose: To examine association between Medicaid cost-containment policies and clinical outcomes

Grant: Donald W. Reynolds Foundation; 9/1/03-8/31/07; National Institute of Aging (Sachs)

Purpose: Faculty Development in Geriatrics

Grant: Robert Wood Johnson Foundation Clinical Scholars Program; 7/1/03-7/1/06; Robert Wood Johnson Foundation (Lantos)

Purpose: To provide a post-residency academic program that trains scholars to apply pure research methods to health-related problems.

Grant: 1 H39 OT 00086-01; 10/01/01-09/30/04; Health Resources and Services Administration Division of Transplantation (Lang)

Purpose: To develop, implement, and assess a corporate workplace intervention designed to increase intention to become an organ donor

Grant: 5 K12 AG00488; 09/01/96-08/31/04; National Institute of Aging (Sachs)

Purpose: Geriatric Academic Program Award

ACADEMIC SERVICE

2020-2023	Faculty Executive Committee (Member), Department of Epidemiology, JHSPH
2018-2021	Honors and Awards Committee (Chair), Department of Epidemiology, JHSPH
2016	Faculty Search Committee (John Jackson), Department of Epidemiology, JHSPH
2015	Faculty Search Committee (Mara McAdams), Department of Epidemiology, JHSPH
2015	Faculty Search Committee, Johns Hopkins Berman Institute of Bioethics
2014-2015	Graduate Training Program in Clinical Investigation (GTPCI) Review Committee
2014-2017	Admissions and Credentials Committee, Department of Epidemiology, JHSPH
2014-	Technology Transfer Committee, JHSPH
2013-2017	Curriculum Committee, Department of Epidemiology, JHSPH
2010-2012	Diabetes Research and Training Center, University of Chicago
2006-2010	Biological Sciences Division Institutional Review Board Member
2006	Steering Committee, Conference on Pharmaceutical Policy, Chicago, Illinois
2006-2008	Steering Committee, DOM Research Day, University of Chicago
2006-2008	Steering Committee, UOC Program in Pharmaceutical Policy, University of Chicago
2005-2006	Search Committee, UOC Comprehensive Cancer Center, Population Science Director
2003-2012	MacLean Center Ethics Committee, University of Chicago
2003-2008	Medicine and the Social Sciences, Co-Chair, University of Chicago
2000-2001	General Medicine Interest Group, Co-Chair, UPHS
2000-2001	Residency Review Committee, Class Officer, UPHS
1999-2001	Hospital of the University of Pennsylvania Ethics Committee, UPHS
1996-1997	Rainbow Babies and Children's Hospital Ethics Committee, CWRU
1994-1996	Class Officer and Chair, Committee of Student Representatives, CWRU

INVITED SEMINARS OR ROUND TABLES

Local or Regional

1. Racial differences in access and outcomes of kidney transplantation. Workshop on medicine and the social sciences. University of Chicago. November 2002.
2. Public support for physician deception of insurance companies. Council on ethical and judicial affairs, American Medical Association. Chicago, IL. April 2003.
3. Truth and lies: are the rules different for lawyers? Panel discussion at the American Bar Association Conference on Professional Responsibility. May 2003.
4. Patient-physician communication about out-of-pocket costs. Northwestern University, December 2002.
5. Patient-physician communication about out-of-pocket costs. Program in Medicine, Arts, and the Social Sciences. University of Chicago. Feb 2004.
6. Patient-physician communication about out-of-pocket costs. Program in Medicine, Arts, and the Social Sciences. University of Chicago. February 2004.
7. Is prescription choice rational? By whose standards? Pharmaceutical innovation and regulation: an American dilemma. Faculty workshop, University of Chicago. February 2004.
8. The doctor-patient relationship in the post-managed care era. American Medical Association. Chicago, IL. May 2004.
9. National trends in Cox-2 inhibitor use since market release: the non-selective diffusion of a selectively cost-effective innovation. Center for Pharmacoeconomics Research, University of Illinois School of Pharmacy. July 2004.
10. Division of Geriatrics Grand Rounds, University of Chicago Hospitals. A framework for medication prioritization and discontinuation. December 2004.
11. Department of Medicine Grand Rounds, University of Chicago Hospitals. Pharmaceutical innovation and the doctor-patient relationship: understanding the diffusion of Cox-2 inhibitors from 30,000 feet to the ground level. February 2005.
12. Bioethics Interest Group, Stritch School of Medicine, Loyola University. Physician deception of insurance companies. April 2005.
13. Midwest Center for Health Services and Policy Research. Hines Veterans Affairs System, Hines, IL. The diffusion of pharmaceutical innovation in the Veterans Affairs Health System. November 2005.
14. American Medical Student Association Panel Discussion. Pritzker School of Medicine, University of Chicago. Discussed role of industry in physician education and prescribing. November 2005.
15. Bioethics Interest Group. Pritzker School of Medicine, University of Chicago. Empiric ethics . . . or . . . what do numbers have to do with right and wrong? February 2006.

16. Chicago Medical Society. Panel discussion on medical ethics. Holiday Inn – Chicago Mart Plaza. Chicago, IL. March 2006.
17. Ethics dinner discussion with students from Pritzker Medical School, University of Chicago, May 2006.
18. The road less traveled – career paths in general internal medicine. National Youth Leadership Forum on Medicine, Chicago, IL. June 2006.
19. The Union League. Ethics considerations in pandemic planning. Chicago, IL. October 2006.
20. Attention: You have just entered the cost-sharing era: ethical, policy, and clinical considerations. Department of Medicine Research Series, December 2006.
21. Pharmacoths and pharmacothat: exploring topics in pharmaceutical research. University of Chicago Division of General Medicine Outcomes Group. March 2007.
22. Thinking globally, acting locally: a Chicagoland collaboration to unravel the impact of the Medicare Prescription Drug Benefit. TAP Pharmaceuticals. Chicago Midwest ISPOR Meeting. April 2007.
23. What do general internists do, and why? National Youth Leadership Forum on Medicine, Chicago, IL. June 2007.
24. The best of times, the worst of times: clinical decision-making and prescription choice in the 21st Century. Department of Otolaryngology. University of Chicago. October 2007.
25. What do we know about health care provider interaction with the pharmaceutical industry? University of Illinois Medical Center at Chicago Clinical Ethics Conference. March 2008.
26. Asking the right question(s) and getting funded to do so. University of Illinois at Chicago Advanced methods and grant writing workshop. March 2008.
27. Challenges and opportunities examining the off-label use of prescription medicines. Institute for Healthcare Studies. Northwestern University, Chicago, IL, May 2008.
28. Improving pharmacotherapy during outpatient care. Primary care medicine today (PRIMED) conference. Rosemont, IL, February 2009.
29. Choosing a research question: the perennial dilemma of “what shall I study”? Midwest Hospitalist Meeting. Chicago, IL. October 2009.
30. Conflicts of interest in medicine. Pritzker School of Medicine, University of Chicago. May 2010.
31. Using social network methods to study prescription drug uptake and diffusion. Department of Health Studies. University of Chicago. November 2010.
32. Managing risk through ethical practice. ISMIE Mutual Insurance Company. Chicago, IL 2010.
33. Overview of Clinical Epidemiology, in Fundamentals of Epidemiology. Johns Hopkins Krieger School of Arts and Sciences. November 2012.

34. The Prescription Opioid Epidemic: In Search of Mission Control.
 - Johns Hopkins Welch Center for Prevention, Epidemiology and Clinical Research Grand Rounds. December 2012.
 - University of Maryland Department of Pharmaceutical Health Services Research. April 2013.
 - Johns Hopkins Department of Medicine Osler Grand Rounds, October 2013.
 - Anne Arundel Medical Center Department of Medicine Grand Rounds, January 2014.
35. Drugs and Aging, in Epidemiology of Aging. Johns Hopkins Bloomberg School of Public Health. May 2013.
36. Career Development, in Public Health Economics Seminar. Johns Hopkins Bloomberg School of Public Health. September 2013.
37. The Effect of FDA Risk Communications on Patient, Provider and Firm Behavior. Johns Hopkins Department of Psychiatry Research Conference, December 2013.
38. Managing Prescription Opioids In Workers Compensation Programs. American Insurance Association. Washington, DC. June 2014.
39. Secondary Data Analysis. General Internal Medicine Fellows Conference. Johns Hopkins Medicine. Baltimore, MD. September 2014.
40. Center for Medical Technology Policy (CMTTP) Green Park Collaborative Annual Meeting. “Real World Evidence – Defining What “Good” Looks Like”. Panel Discussion. April 2015.
41. Safety, Efficacy and Pharmacokinetic Bioequivalence of Biosimilar TNF- α Inhibitors Compared with their Reference Biologics: A Systematic Review. Department of Clinical Pharmacology, Johns Hopkins Hospital. February 2016.
42. Reducing Prescription Drug Spending: A Review of Policy Options. Johns Hopkins Bloomberg School of Public Health. March 2016.
43. Keynote. Managing the Unmanageable: Reining in the Opioid Epidemic. CareFirst. Baltimore, Maryland, June 2017.
44. Moderator. Epidemiology Inclusion, Diversity, Equity & Science (Epi IDEAS) Communication with Policy Makers: The Opioid Epidemic. Panel Discussion featuring Lauren Jee and Amanda Latimore. Johns Hopkins Bloomberg School of Public Health. Baltimore, Maryland, January 2019.
45. Round Table Participant. National Center for Health Statistics. Data Dissemination of New Data: Alignment of Infrastructure Improvements on Opioid Use and Overdose with Researchers’ Needs and Interests. Rockville, Maryland, July 2019.
46. Johns Hopkins Department of Pathology Symposium. The Opioid Epidemic. Baltimore, Maryland, September 2019.
47. Johns Hopkins Department of Epidemiology. Pivotal Trials for FDA-Approved Novel Therapeutic Agents: How Good is the Science, and What Does It Cost? Baltimore, Maryland, September 2019.

National or International

48. Panel discussion of interdisciplinary health professions education. Ohio League of Nursing Annual Meeting, Cleveland, Ohio, October 1996.
49. Grand Rounds, Department of Medicine, University of Pennsylvania: Pharmaceutical industry sponsorship of continuing medical education: training physicians or marketing products? June 2001.
50. Patient-physician communication about out-of-pocket costs. University of Michigan, January 2003.
51. Patient-physician communication about out-of-pocket costs. MetroHealth Medical Center, January 2003.
52. “Luxury care”, professional standards, and personal choice: ethical and professional issues in retainer medical practices. Panel discussion at the American Society of Bioethics and Humanities Annual Meeting. October 2004.
53. Ad hoc pharmacoeconomics working group. AstraZeneca LP. Patient-physician communication about out-of-pocket costs. June 2005.
54. How much should \$38 billion buy? The uptake and impact of the Medicare Part D Prescription Benefit. Department of Medicine. VA Center for Health Equity Promotion and Research and University of Pittsburgh Department of Medicine. December 2007.
55. The Medicare Modernization Act Prescription Drug Benefit. Department of Ambulatory Care and Prevention, Harvard Medical School. January 2008.
56. Principles of survey research. Patan Academy of Health Sciences. Kathmandu, Nepal, April 2008.
57. Health care publishing in the peer-reviewed literature. Patan Academy of Health Sciences. Kathmandu, Nepal, April 2008.
58. Impact of FDA regulatory advisories on patient, provider and firm behavior. Mayo Clinic, April 2010; Virginia Commonwealth University, October 2010; Yale University, November 2010; Johns Hopkins University School of Medicine, November 2010; Johns Hopkins University School of Public Health, June 2011.
59. Special Guest: FED UP: Rally for a Federal Response to the Opioid Epidemic, National Sylvan Theater Stage at the Washington Monument, Washington DC, September 2014.
60. Panelist: Art and Science of Scientific Communications. CBI Advanstar. Publication Planning Forum. Philadelphia, PA. December 2014.
61. CMS Grand Rounds: The Opioid Epidemic. CMS Headquarters, Baltimore, MD. November 2015.
62. Panelist: Drug Safety and Surveillance. FDA/CMS Summit. IIR/IBC Life Sciences. Ritz Carlton Hotel, Washington DC, December 2015.
63. Special Guest: The Opioid Epidemic. American Insurance Association: Workers’ Compensation Committee. Washington DC, February 2015.

64. Safety, Efficacy and Pharmacokinetic Bioequivalence of Biosimilar Tumor Necrosis Factor-alpha Inhibitors Compared with their Reference Biologics: A Systematic Review. Harvard Pilgrim Health Care. March 2016.
65. The Opioid Epidemic. Johns Hopkins Department of Pharmacy Grand Rounds. May 2016.
66. Guest Speaker: Innovations in Diabetes Care. Academy of Managed Care Pharmacy. Alexandria, Virginia, July 2016.
67. Panelist: Needed Changes in Federal Policy and Legislation to Address Nation's Opioid Crisis. Educational Briefing for Congressional Members and Staff. Washington, DC, September 2016.
68. Panelist: Balancing Opioid Access and Use. Academy of Managed Care Pharmacy Annual Research Symposium. Alexandria, Virginia, October 2016.
69. Keynote. An Evidence-Based Approach to the Opioid Epidemic. National Academy for State Health Policy. Pittsburgh, Pennsylvania, October 2016.
70. Special Guest Speaker. Science, Public Health and the Prescription Opioid Industry. Motley Rice LLC. Washington, DC, June 2017.
71. Guest Speaker. Opioid Prescribing Practices. Bloomberg Philanthropies. January 2018.
72. Plenary Speaker. Conundrums in Biotechnology: How Does Quality Impact Safety. World Congress of Biopharmaceuticals. Washington, DC, February 2018.
73. Special Invited Speaker. "Covering the Opioid Crisis". National Press Foundation. Washington, DC, February 2018.
74. Guest Panelist. "Addressing Prescription Drug Costs". Johns Hopkins Carey School of Business Drug Accessibility and Pricing Symposium. Baltimore, MD, March 2018.
75. Guest Panelist. "Best Practices in Opioid Prescription, Pain Management, Medicine-Assisted Treatment and Recovery: New Models of Care for Opioid Use Disorder". Modern Healthcare Opioid Symposium. Baltimore, MD, April 2018.
76. Invited Speaker. "Comparative Safety of NSAIDs and Opioids Among Hospitalized Patients: A Case Study". Premier Annual Breakthroughs Conference. Nashville, TN, June 2018.
77. Guest Speaker. National Governor's Association. Opioid Coverage Policy Roundable. Washington, DC, June 2018.
78. Invited Panelist. National Black Caucus Foundation. Protecting the Health, Safety and Security of African American Communities. Health and Wellness Luncheon. Washington, DC, September 2018.
79. Session Moderator. State Legislative Leaders Foundation (SLLF) Fall Issues Summit. Addressing the Opioid Crisis. Baltimore, MD, September 2018.

80. Panelist. “Addiction Research – What is New and What is Interesting?” and “Why Recovery Research Matters and Why Residents and Alumni Should Participate”. Oxford House World Convention. Kansas City, MO, October 2018.
81. Facilitator. Academy of Managed Care Pharmacy Partnership Forum: “Building the Foundation for Patient-Reported Outcomes: Infrastructure and Methodologies”. Orlando, FL, November 2018.
82. Invited Panelist. National Academies of Science, Engineering and Medicine. “The Role of Nonpharmacological Approaches to Pain Management.” Washington, DC, December 2018.
83. Medicine Grand Rounds. Weill Cornell Medicine. “The Opioid Epidemic: Grief and Hope in the New Year”. New York, NY, January 2019.
84. Invited Panelist. OpioidX: New Approaches to Addressing the Opioid Crisis. MIT Sloan School of Management. Laboratory for Financial Engineering. Boston, MA, November 2020.
85. Invited Panelist. Electronic Prescribing of Controlled Substances (EPCS). American Medical Informatics Association. November 2020.
86. Invited Instructor. Academy of Managed Care Pharmacy (AMCP) Annual Meeting. Evidence behind COVID-19 Treatments and Vaccines. March 2021.

NARRATIVE

G. Caleb Alexander, MD, MS is a Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health, where he serves as a founding co-Director of the Center for Drug Safety and Effectiveness and Principal Investigator of the Johns Hopkins Center of Excellence in Regulatory Science and Innovation (CERSI). He is a practicing general internist and pharmacoepidemiologist and is internationally recognized for his research examining prescription drug utilization, safety and effectiveness. Dr. Alexander is the author of over 300 scientific articles and book chapters, many using primary or secondary data to characterize the epidemiology of prescription opioid use in the United States as well as to evaluate the effect of federal and state regulatory and payment policies on opioid prescribing, dispensing and utilization. He has extensive experience disseminating these findings to both professional and lay audiences and has testified in front of both the U.S. House of Representatives and the U.S. Senate regarding his team’s work. He is also one of three editors of a widely cited monograph produced by the Johns Hopkins Bloomberg School of Public Health that has provided comprehensive and concrete, evidence-based recommendations for addressing the opioid epidemic. Dr. Alexander received his B.A. cum laude from the University of Pennsylvania, an MD from Case Western Reserve University, and a Master of Science from the University of Chicago.

KEYWORDS

Pharmacoepidemiology, pharmaceutical policy, regulation, internal medicine, opioids, opioid use disorder

Abatement Plan for Addressing the Opioid Crisis in Lake County and Trumbull County

Expert Witness Report of G. Caleb Alexander, MD, MS

Appendix C: Expert Witness Engagements

State of Washington v. McKesson Corp. et al., Case No. 19-2-06975-9
Washington Superior Court, King County
Testimony regarding abatement
Report submitted January 20, 2021

People of California, acting by and through Santa Clara County et al. v. Purdue Pharma L.P. et al., Case No. 30-2014-00725287-CU-BT-CXC
California Superior Court, Orange County
Testimony regarding abatement
Deposed on February 16, 2021
Report submitted November 13, 2020

In re: National Prescription Opiate Litigation, Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio
Second bellwether trial track involving Cabell County and City of Huntington, West Virginia
Testimony regarding abatement
Deposed on September 20, 2020
Report submitted August 3, 2020

Tucson Medical Center v. Purdue Pharma L.P. et al., Case No. C20184213
Arizona Superior Court, Pima County
Testimony regarding abatement
Report submitted August 10, 2020

State of Montana v. Purdue Pharma L.P. et al., Case No. 1:17-md02804
Montana First Judicial District Court, Lewis & Clark County
Disclosed; no testimony given

State of Washington v. Purdue Pharma L.P. et al., Case No. 17-2-255055-0 SEA
Washington Superior Court, King County
Testimony regarding abatement
Report submitted July 8, 2019

In re: National Prescription Opiate Litigation, Case No. 1:17-MD-2804

U.S. District Court for the Northern District of Ohio

First bellwether trial track involving Cuyahoga County and Summit County, Ohio

Testimony regarding abatement

Deposed on April 26, 2019

Report submitted March 25, 2019

Supplemental Report submitted April 3, 2019

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Abatement Plan for Addressing the Opioid Crisis in Lake County and Trumbull County

Expert Witness Report of G. Caleb Alexander, MD, MS

Appendix F: Potential Indicators of High-Risk Opioid Distribution

1. Identifying high-risk medication use is an integral component of comprehensive risk management and risk mitigation programs within the pharmaceutical supply chain. One method to identify such high-risk use is through the application of “indicators” that merit further inquiry and that are based on patterns of pharmaceutical distribution, dispensing, prescribing, or utilization.^a I reviewed the portion of Carmen Catizone’s Expert Report in which he identifies indicators that are triggered based on information about prescriptions, patients, and prescribers, and which have been recognized by Defendants and/or law enforcement.^{1,2,3} These indicators are listed in Table 1 below. As described in this appendix, these types of indicators rely on an extensive evidence base that links them with an increased risk of opioid-related adverse events including addiction, overdose, and death. These indicators have been, or can be, used to manage and improve the safety and quality of health care delivery.

2. Frequency, dose, and duration. Some indicators capture potentially inappropriate or “high-risk” opioid prescribing. Examples of such indicators include those triggered based on: frequency of opioid fills; volume of opioids or controlled substances prescribed; high morphine milligram equivalents (MME) per day; and opioid duration measured in days’ supply.^{4,5,6} A higher frequency of opioid fills may be an indicator for opioid misuse, dependence, or pain control that may be better managed by non-opioid treatment, and warrants prescriber follow up.⁷ Additionally, a higher frequency of opioid fills may result in a greater likelihood of overlapping days’ supply and higher MME per patient. Criteria based on opioid dose and duration are also important because there is an unequivocal dose-response association between opioid dose and duration and opioid-related morbidity and mortality.^{8,9,10,11,12,13,14} For example, in a study of Medicare beneficiaries from 2008 to 2012, those who had opioid prescriptions that summed to >210 days within a 180-day period had a 3.5-times higher risk of opioid overdose relative to patients treated with opioids who did not have a surplus of days’ supply.¹⁵ Similarly, in an analysis of individuals with chronic pain without substance use disorder, those treated with long-acting opioids had at least a threefold higher rate of unintentional overdose compared to those treated with non-opioid pharmacologic treatments.¹⁶ A 2016 analysis using Maryland’s Prescription Drug Monitoring Program (PDMP) found patients treated with ≥ 120 MME per day had nearly two-times higher risk of fatal opioid overdose than those who received <50 MME per day; the analysis also identified two-times higher odds of overdose among individuals receiving 2-3 short-acting opioid fills in six months, and three-times higher odds of overdose among individuals receiving 4 or more short-acting opioid fills in six months.¹⁷ Moreover, an analysis of Massachusetts’ PDMP data from 2011 to 2015 found that patients who received ≥ 100 MME for three or more months had six-times higher risk of fatal opioid overdose than their counterparts.¹⁸ Finally, a longitudinal, prospective cohort study from 2002 to 2012 found that prior receipt of high-dose opioid prescriptions (≥ 90 MME per day) was associated with 2.5-times higher risk of subsequent heroin use compared to participants who did not receive high-dose prescription opioids.¹⁹

3. Concomitant prescriptions. The concomitant use of opioids with other controlled substances, such as benzodiazepines and other sedatives, has long been known²⁰ to significantly increase the risk of respiratory depression and is cautioned against by the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and other authoritative

^a While I use the term “indicators” throughout, scientific articles that I cite use varied terminology to refer to these such as “flags,” “triggers” or “alerts”.

bodies.^{21,22,23,24,25,26} Data and systems-level approaches to identify the risk of different types of opioids and concurrent use of opioids with medications such as benzodiazepines have been available to the healthcare sector for decades.^{27,28} In 2000, 15.6% of prescription opioid overdose deaths in the United States (U.S.) involved benzodiazepines; by 2017, the prevalence of benzodiazepine co-involvement among prescription opioid overdose deaths increased to 33.1%.²⁹ A study using Maryland's PDMP data found that patients treated with opioids who received two or more benzodiazepine fills within six months had over three-times greater odds of fatal opioid overdose, and separately, illicit opioid overdose, compared to patients who did not receive benzodiazepines;³⁰ individuals with at least one muscle relaxant fill had over two-times greater odds of opioid overdose compared to those who did not receive muscle relaxers. Another study found that individuals who received overlapping opioid and benzodiazepine prescriptions over three months had two-times higher risk of non-fatal opioid overdose and seven-times higher risk of fatal opioid overdose compared to patients who did not receive benzodiazepines.³¹ In addition to an increased risk of overdose, the concomitant use of opioids and other controlled substances may also indicate non-medical use.³²

4. Prescriber activity. Multiple prescriptions written by a single prescriber for the same opioid, dose, and duration may also be associated with opioid non-medical use and diversion. This behavior may be associated with what have been colloquially termed “pill mills,” or locations where the prescribing of large quantities of controlled substances outside of the scope of standard medical practice takes place.^{33,34} Crackdowns on “pill mills” received substantial media attention and resulted in increased scrutiny and Drug Enforcement Administration (DEA) regulations surrounding the prescribing of opioids and other controlled substances in the late 2000s and early 2010s.³⁵ However, as with “opioid shopping,” this behavior and diversion represent a small proportion of providers that prescribe opioids and patients that receive opioids.³⁶
5. Conversely, patients that have prescriptions for controlled substances from multiple providers may be an indication of non-medical use and has been referred to, by some, as “doctor shopping” or “opioid shopping.” Within the literature, it is common to use cutoffs of ≥ 4 or ≥ 5 different prescribers for controlled substances, within a specific timeframe such as three or six months, as a potential indicator of misuse.^{37,38,39} An analysis of Medicare beneficiaries who were treated with opioids between 2008 and 2012 found that those who received opioid prescriptions from five or more prescribers had over a four-times higher risk of opioid overdose compared to their counterparts with fewer prescribers.⁴⁰
6. Number of pharmacies used. Filling prescriptions at a single pharmacy promotes continuity of care as well as greater supervision and monitoring of an individual's prescriptions. A study of Massachusetts' PDMP data from 1996 to 2006 found that nearly 90% of patients used only one pharmacy and three or fewer prescribers for their controlled substances.⁴¹ By contrast, the risk of potential opioid misuse, diversion, and overdose often increases with the number of pharmacies used. For example, in a longitudinal, multistate cohort of Medicaid enrollees, the use of multiple pharmacies was associated with significantly elevated risk of opioid overdose compared to individuals using one pharmacy alone after accounting for dose level, demographic characteristics, and preexisting history of addictive behaviors.⁴² Similarly, in an analysis of health insurance claims, having four or more pharmacies for the same drug was

associated with increased opioid misuse.⁴³ A case-control study using PDMP data from West Virginia found that individuals with drug-related death were 13-times more likely to visit four or more pharmacies within the six months prior to their death compared to a group of similar individuals who did not die.⁴⁴ Another study found that patients who filled their opioids at four or more pharmacies within three months had two-times higher risk of non-fatal opioid overdose and nearly five-times higher risk of fatal opioid overdose.⁴⁵ Yet another analysis of individuals treated with opioids between 2008 and 2012 found that those who obtained opioids from five or more pharmacies had 5.5-times higher risk of opioid overdose compared to those who used fewer than five pharmacies.⁴⁶ These studies support many others demonstrating that the use of multiple pharmacies is an independent risk factor for opioid misuse,^{47,48} non-fatal overdose,⁴⁹ and death.⁵⁰

7. Distance traveled. Other indicators may be based on the distance that individuals have traveled to obtain or fill prescription opioids. Individuals may use multiple providers or pharmacies further from their homes in order to access providers with a greater willingness to prescribe controlled substances or to evade detection of misuse or diversion.^{51,52} An 18-month retrospective cohort study in 2008 using a large U.S. prescription database determined that “opioid shopping,” defined as the overlapping supply of opioids written by more than one prescriber at three or more pharmacies, was associated with significantly greater distance traveled.⁵³ Nearly one in five “shoppers” and nearly one in four “heavy shoppers” - individuals with five or more “shopping” episodes - traveled to two or more states. The study found that fewer than one in twenty “non-shoppers” traveled to two or more states for prescriptions. The median of the maximum distance that “shoppers” and “heavy shoppers” traveled was 12.6 miles (interquartile range [IQR]: 5.6-47.4) and 15.0 miles (IQR: 6.9-77.0), respectively. In contrast, “non-shoppers” traveled a median of 0.0 miles (IQR: 0-2.6). Similarly, a 2015-2016 analysis of Arkansas PDMP data characterized individuals with above average patient-to-prescriber travel wherein patients bypass nearby prescribers in favor of more distant ones. Such individuals were associated with high-risk opioid use such as concomitant benzodiazepine-opioid use or the use of ≥ 90 MME per day.⁵⁴ Separately, an analysis of Medicare beneficiaries treated with opioids between 2008 and 2012 found that those with an out-of-state prescriber or pharmacy, respectively, had 2.3- and 1.8-times higher risk of opioid overdose compared to those who did not travel out of state.⁵⁵
8. Early refills. Early refills of opioids have long been recognized as an indicator for opioid misuse and diversion.^{56,57,58} An analysis of the commercially insured in Maine suggested that those with early opioid refills had more than three-times greater odds of opioid misuse compared with their counterparts.⁵⁹ A 2017 analysis using all-payer dispensing data and which defined early refills as a refill occurring at least five days before the end of the initial days’ supply, found that among patients who received at least two opioid prescriptions, 9.6% had an early opioid refill and 2.4% had two or more early refills in one year.⁶⁰
9. Method of payment. Cash payment for prescriptions, despite health insurance coverage, has also been associated with opioid diversion,⁶¹ and fatal and non-fatal opioid overdoses. An 18-month analysis of 2008 longitudinal, all-payer pharmacy claims found that nearly half (44.9%) of individuals with “opioid shopping” behavior paid in cash compared to one in five (18.5%) individuals without such behavior.⁶² In a follow-up study, individuals paying cash also had

greater odds of non-medical opioid use than their Medicare or commercially insured counterparts.⁶³ Additionally, a study of PDMP data from 2011 to 2015 found that patients who filled opioids and had three or more cash payments for medications in three months had a 130% higher rate of non-fatal opioid overdose and 280% higher rate of fatal opioid overdose.⁶⁴

10. Role of pharmacies and pharmacists in addressing the opioid epidemic. Pharmacies and pharmacists play an important role in addressing the opioid epidemic given their position within the pharmaceutical supply chain and face-to-face interactions with patients. First and foremost, pharmacies and pharmacists should follow-up on indicators of opioid misuse, since they have the authority to refuse prescription fills or to gather further information so as to allow for the dispensing of controlled substances under the safest conditions possible.⁶⁵ Pharmacies, and particularly pharmacists, are also ideal points for patient education and outreach on the risks of overdose,⁶⁶ and to implement programs for screening and referrals to OUD treatment.⁶⁷ Pharmacies are also well-positioned to implement drug disposal or deactivation packets for individuals filling prescriptions for controlled substances (see also Section 1C of Expert Report),⁶⁸ as well as harm reduction initiatives such as naloxone prescribing and dispensing (see also Section 2E of Expert Report).^{69,70,71,72} However, pharmacists report that time constraints that result from organizational policies, such as those that arise from insufficient staffing or time requirements for filling a prescription, hinder their review of concerning patient behavior or prescribing practices.^{73,74}

Table 1. Select Examples of Potential Indicators to Safeguard the Pharmaceutical Supply Chain.

Concept	Examples
Frequency, Dose, and Duration	<ul style="list-style-type: none"> • Large opioid prescription volume (e.g., ≥ 90 MME per day) • Several long- or short-acting opioid prescriptions within a three- or six-month window • Cumulative days' supply within a three- or six-month window
Concomitant Prescriptions	<ul style="list-style-type: none"> • Combinations of opioids, benzodiazepines or other sedatives, and muscle relaxants from one or more provider • Concomitant fills of short- or long-acting opioid prescriptions
Prescriber Activity	<ul style="list-style-type: none"> • Use of multiple prescribers (e.g., ≥ 4, ≥ 5) for controlled substances within a three- or six-month window • Multiple individuals have prescriptions from a single prescriber on the same day, or within a single week, with the following characteristics: <ul style="list-style-type: none"> ○ Single type of opioids (e.g., hydrocodone, short-acting opioids, long-acting opioids) ○ Same dose ○ Same duration ○ Cash payment
Number of Pharmacies Used	<ul style="list-style-type: none"> • Use of multiple pharmacies to fill concurrent prescriptions of: <ul style="list-style-type: none"> ○ Opioids (e.g., different formulations, short-acting, long-acting) ○ Opioids with other controlled substances (e.g., benzodiazepine, sedative, or muscle relaxer) • Pharmacies may be further classified by pharmacy type (e.g., chain [same parent, different parent], independent, mass merchandizer)
Distance Traveled	<ul style="list-style-type: none"> • Individual lives significant distance from provider issuing opioid prescription and/or pharmacy where the prescription is filled^b • Provider issuing opioid prescription is located in a different state or county from the pharmacy dispensing it
Early Refills	<ul style="list-style-type: none"> • Early refill requests for opioids or concurrent fills of opioids and other controlled substances
Method of Payment	<ul style="list-style-type: none"> • Individuals with chronic pain or prior opioid fills paying with cash • Individuals paying for controlled substances with cash, despite having health insurance coverage

MME morphine milligram equivalent

^b This distance will depend on geographic and demographic factors, such as rurality and density of pharmacies in a patient's home zip-code, which can be incorporated into algorithms that identify flags.

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